

EPA Registration No.
11556-115
Vol. 1

Linda
DeLuise
9/27/01



Agriculture Division

Animal Health

via Federal Express

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 268-2000

September 24, 2001

Mr. George LaRocca
Product Manager
Registration Division (H7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Labelling in accordance with the Coumaphos RED
EPA Reg. No.'s 11556-4, -11, -14, -23, -98, -115
✓ ✓ ✓ ✓ ✓ ✓

Dear Mr. LaRocca:

As per your letters dated August 21, 2001, Bayer Corporation is sending this letter as notice of intent to revise the labels in accordance with the Agency's reviews for the above referenced products. The revised labels will be sent under separate cover to your attention as soon as they are available.

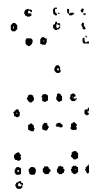
If you have any questions, please do not hesitate to call me at (913) 268-2588 or Greg Gagliano at (913) 268-2751.

Sincerely,

F. Terry McNamara
Director, Preclinical Development

FTM:GGG/lt

cc: Linda A. DeLuise (7505C)



EPA REG. NO.

[illegible]

(F9)

Bayer HealthCare
Animal Health Division



June 30, 2004

Document Processing Desk – Final Printed Labeling
Office of Pesticide Programs – 7504 C
U. S. Environmental Protection Agency
1801 South Bell Street
Arlington, VA 22202

SUBJECT: Final Printed Labeling

Dear Sir/Madam:

Enclosed are two copies of Bayer HealthCare's Animal Health Division final printed labeling for the following pesticide products:

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201

Phone: 913 268 2000

EPA Reg. No.	Product Name	EPA Product Manager
11556-137	QuickBayt Fly Bait	Dan Kenny, 4A
11556-140	QuickBayt Disposable Fly Bait Strip	Dan Kenny, 4A
11556-98	Co-Ral Flowable Insecticide	George LaRocca, 13
11556-115	Co-Ral Fly and Tick Spray	George LaRocca, 13
11556-107	CyLence Pour-On Insecticide	George LaRocca, 13
11556-136	Tempo 1% Dust Insecticide	George LaRocca, 13

Thank you for your attention to this matter. Please call me at 913-268-2311 or email at mary.hunt.b@bayer.com if you have any questions.

Respectfully,

BAYER HEALTHCARE, LLC
ANIMAL HEALTH DIVISION

Mary McKinney Hunt
Regulatory Specialist

enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-98	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Flowable Insecticide	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 9/10/2002
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. Terry McNamara	Title Director, Preclinical Dev & Reg Affairs	Telephone No. (Include Area Code) (913) 268-2688	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <i>F. Terry McNamara</i>	3. Title Director, Preclinical Development & Regulatory Affairs		
4. Typed Name F. Terry McNamara	5. Date 7/15/04		

RESTRICTED USE PESTICIDE

Due to Acute Oral Hazard—For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification. Use restricted to employees of the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) who are enrolled in the USDA-APHIS cholinesterase monitoring program.

Co-Ral®

(coumaphos)

Flowable Insecticide



**For Control Of Scabies On Cattle And For Control Of Horn Flies, Lice, Ticks And
Screwworms On Beef And Non-Lactating Dairy Cattle And Horses**

ACTIVE INGREDIENT: O,O-Diethyl O-(3-chloro-4-methyl-2-oxo-(2H)-1-benzopyran-7-yl) phosphorothioate	42.0%
OTHER INGREDIENTS	58.0%
TOTAL	100.0%

Product contains 4.2 lbs of coumaphos per gallon
Shake Well Before Using

EPA Reg. No. 11556-98 EPA Est. No. 3125-MO-1

KEEP OUT OF REACH OF CHILDREN

DANGER POISON
PELIGRO

Fatal if swallowed. May be fatal if inhaled. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing.
Do not breath spray mist.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

2 Gallons (7.6 L)



Bayer

Manufactured for
Bayer HealthCare LLC, Animal Health Division, Shawnee Mission, Kansas 66201 U.S.A.

HAZARDS TO DOMESTIC ANIMALS (CATTLE AND HORSES)

Acute symptoms of overdosage in cattle and horses are: frequent defecation and urination, watering of eyes and muscular twitching. Later the symptoms are: salivation, diarrhea and muscular weakness.

While no claims for control of cattle grubs are made for this product, host parasite reactions such as bloat, salivation, staggering and paralysis may sometimes occur when cattle are treated while the common cattle grub (*Hypoderma lineatum*) is in the gutlet, or while the northern grub (*H. bovis*) is in the area of the spinal cord. Cattle should be treated either *before* or *after* these stages of grub development. Consult your veterinarian, extension livestock specialist or extension entomologist regarding the timing of the grub cycle for your cattle based on their origin and history.

Consult a veterinarian at the first sign of adverse reaction.

NOTE. If it is impossible to determine the origin of the cattle, and thus the exact stage of the grubs is unknown, it is recommended that the cattle receive only a maintenance ration of low energy feed during the treatment period. This lessens the likelihood of severe bloat which may occur in cattle on full feed when the common grub is killed while in the gutlet.

NOTICE TO VETERINARIAN: If the proper dosage of Co-Ral Flowable Insecticide has been applied and adverse reactions such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine sulfate by injection is antidotal.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, birds, fish and aquatic invertebrates. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Not for storage in or around the home. Store in a cool, dry place.

CATTLE DIP SOLUTION DISPOSAL: The Agency requires that spent dip vat solution be bioremediated, and recommends the bioremediation method developed by the USDA. The treated solution must be transferred to shallow, concrete-lined evaporation ponds for further degradation. The evaporation ponds must be constructed to prevent overflow or flooding during wet seasons and must be lined with reinforced concrete. Dried sludge generated in the evaporation ponds must not be applied to agricultural land and should be disposed according to solid waste disposal regulations established by your local and/or state Environmental Control Agency. Questions concerning the disposal of spent solution should be directed to the waste representative at the nearest EPA Regional Office.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your state Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE: THE DIRECTIONS ON THIS LABEL WERE DETERMINED THROUGH RESEARCH TO BE APPROPRIATE FOR THE CORRECT USE OF THIS PRODUCT. THIS PRODUCT HAS BEEN TESTED UNDER DIFFERENT ENVIRONMENTAL CONDITIONS BOTH INDOORS AND OUTDOORS SIMILAR TO THOSE THAT ARE ORDINARY AND CUSTOMARY WHERE THE PRODUCT IS TO BE USED. INSUFFICIENT CONTROL OF PESTS OR PLANT INJURY MAY RESULT FROM THE OCCURRENCE OF EXTRAORDINARY OR UNUSUAL CONDITIONS, OR FROM FAILURE TO FOLLOW LABEL DIRECTIONS. IN ADDITION, FAILURE TO FOLLOW LABEL DIRECTIONS MAY CAUSE INJURY TO ANIMALS, MAN, AND DAMAGE TO THE ENVIRONMENT. BAYER OFFERS, AND THE BUYER ACCEPTS AND USES, THIS PRODUCT SUBJECT TO THE CONDITIONS THAT EXTRAORDINARY OR UNUSUAL ENVIRONMENTAL CONDITIONS, OR FAILURE TO FOLLOW LABEL DIRECTIONS ARE BEYOND THE CONTROL OF BAYER AND ARE, THEREFORE, THE RESPONSIBILITY OF THE BUYER.

Co-Ral® is a Reg. TM of the parent company Bayer HealthCare AG.

00715007-7132650

00715007-7132650, R.11



NOT REVIEWED
In accordance with PR Notice 82-2
based on draft labeling dated

9/10/2002

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read this entire label and Conditions of Sale before using this product.
AVISO - Al Usuario: Si usted no puede leer o entender ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot read or understand English, do not use this product until the label has been fully explained to you.)

APPLICATION RESTRICTIONS

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine sulfate by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not spray in confined, non-ventilated area.

Do not treat areas such as drinking cups, mangers or troughs where livestock feed. Do not contaminate water, food, feedstuffs, feed or feed handling equipment, or milk or meat handling equipment.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with handheld sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.

Entry Restriction: Do not contact or allow contact with treated animals until their coats are dry.

FOR USE ON BEEF AND NON-LACTATING DAIRY CATTLE AND ON HORSES

Co-Ral Flowable has been especially developed to provide a highly concentrated formulation of coumaphos. The physical properties of the formulation allow for quick initial mixing and excellent suspension, as well as ease of resuspension where settling has occurred due to lack of regular use or overwintering.

As a liquid, the difficulties and inconvenience commonly associated with mixing of wettable powders are greatly reduced or eliminated. Because Co-Ral Flowable is a much more concentrated formulation of coumaphos than previously available, a smaller amount is needed to prepare any given volume of spray or dip suspension.

DIP TREATMENT FOR ECTOPARASITES OF CATTLE:

Charge dip vats with accurate concentration by using exact quantity of Co-Ral Flowable and volume of water specified. Mix suspension thoroughly before each use. Passage of animals through the vat does not change concentration of remaining suspension. Water lost by evaporation should be replaced. If water is added to the vat due to rainfall or replenishment, an appropriate amount of Co-Ral Flowable should also be added. Continue to use vat until accumulation of debris makes it unsuitable for further use.

NOTE: Be sure cattle have access to drinking water prior to dipping. Do not dip excessively thirsty animals.

SPRAY TREATMENT FOR ECTOPARASITES OF CATTLE AND HORSES:

Co-Ral Flowable provides residual control of ectoparasites on livestock. Repeat applications will be necessary only when insects reappear and constitute a problem. Co-Ral Flowable mixes easily with water to form a suspension which is readily usable in spray equipment.

APPLICATION RATES

Do not apply more than one (1) gallon of Co-Ral Flowable per 165 gallons of water as a dip or more than one (1) gallon of Co-Ral Flowable per 200 gallons of water as a spray. No withdrawal interval is required between application and use of meat as food.

Parasite	Gallons Co-Ral Flowable	Remarks
Scabies* (Psoroptes bovis)	1	DIP TREATMENT: Mix specified amount in 165 gallons of water. Agitate dip suspension thoroughly prior to each use. Two treatments, 10 to 14 days apart, are necessary to control scabies. Do not dip more than twice per year.** Submerge each animal to assure complete coverage and thorough wetting of the skin.
Horn Flies Lice	1/4 (1 quart)	SPRAY TREATMENT: Add specified amount to 200 gallons of water and mix thoroughly. Apply for complete wetting to run-off. Do not spray more than six times per year. Do not make applications less than 10 days apart.
Ticks*	1/2-1	DIP TREATMENT: Mix specified quantity of Flowable in 200 gallons of water. Agitate dip thoroughly prior to each use to assure uniform treatment. Do not dip more than twice per year.** Do not make applications less than 10 days apart.
	1/2-1	SPRAY TREATMENT: Add specified amount of Flowable to 200 gallons of water and mix thoroughly. Apply for complete wetting to run-off. Do not spray more than six times per year. Do not make applications less than 10 days apart.
Screwworms*	1	SPRAY TREATMENT: Mix specified amount in 200 gallons of water and mix thoroughly. Apply as a high pressure spray to wet the skin, not just the hair. Do not spray more than six times per year. Do not make applications less than 10 days apart.

*Approved as a "Permitted Pesticide" by Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture for the control of Screwworms, Scabies and Ticks in Federal Eradication Programs when used according to the directions of APHIS Veterinary Service Regulations and/or Memoranda.

**Animals should not be dipped more than twice per year unless additional treatments are required by APHIS Veterinary Service Regulations/Memoranda for Animals Included in Federal Eradication Programs.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

FIRST AID

Contains an organophosphate that inhibits cholinesterase.

If swallowed:	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 - 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
<p>Note To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.</p> <p>HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, call 1-877-258-2280. For product information, call 1-800-633-3796.</p>	

DANGER POISON
PELIGRO

PERSONAL PROTECTIVE EQUIPMENT

Wear a respirator with an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter.

Some materials that are chemical-resistant to this product are butyl rubber (≥14 mils) and nitrile rubber (≥14 mils). If you want more options, follow the instructions for Category F on an EPA chemical-resistance category selection chart.

Mixers, loaders, applicators and others exposed to the concentrate (such as during a spill or equipment breakdown) must wear long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron, and face shield or goggles.

Applicators and all other handlers exposed to the diluted product must wear long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from the other laundry.

USER SAFETY RECOMMENDATIONS

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.





U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg.
Number:

11556-
115

Date of Issuance:

SEP 10 2002

NOTICE OF PESTICIDE:
 Registration
 x Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Co- Ral Fly and Tick
Spray

Name and Address of Registrant (include ZIP Code):

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section 3(c)(2)(B).

1. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 11556-115".

Signature of Approving Official:

Date:

page 2
EPA Reg. No.11556-115

2. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Enclosures

Reason to Issue: Amend text as per SRRD
Review Letter (8/21/01) and
PR Notice 2001-1

Date: 08/20/02
Supersedes: 1/16/98
Page 1 of 9

(Front Panel)

Co-Ral®

(coumaphos)

Fly and Tick Spray

For Control of Horn Flies, Face Flies, Lice and Ticks

	Percent by Weight
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
Other Ingredients*:	93.85%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. TBD

KEEP OUT OF REACH OF CHILDREN

WARNING

May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing.

**See Back and Side Panels for First Aid
and Other Precautionary Statements**

NET CONTENTS: 0.50 gallon (1.892 L)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box 390
Shawnee Mission, Kansas 66201

U.S.A. ACCEPTED
with COMMENTS
in EPA Letter Dated

SEP 10 2002

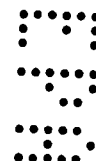
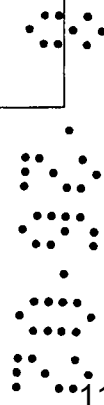
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

11556-115

(Side Panel)

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

FIRST AID	
Contains an organophosphate that inhibits cholinesterase.	
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give <u>any</u> liquid to the person.• Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
Note To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine. Contains petroleum distillate - vomiting may cause aspiration pneumonia.	
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, call 1-877-258-2280. For product information, call 1-800-633-3796.	



(Side Panel)

WARNING
PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are barrier laminate and viton (≥ 14 mils). If you want more options, follow the instructions for Category G on an EPA chemical-resistance category selection chart.

Mixers, loaders, and others exposed to the concentrate (such as during a spill or equipment breakdown) must wear long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron, and face shield or goggles.

Applicators and all other handlers exposed to the diluted product must wear long-sleeve shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from the other laundry.

User Safety Recommendations

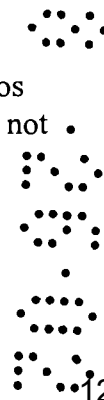
Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, birds, fish and aquatic invertebrates. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.



(Side Panel)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and Conditions of Sale before using this product.

APPLICATION RESTRICTIONS

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Fly and Tick Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at ½ maximum label rate, etc.

(Side Panel)

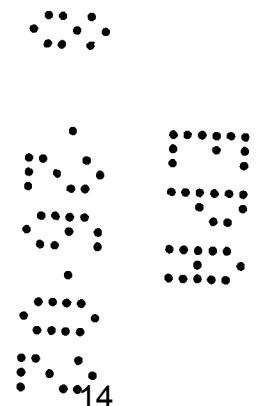
Co-Ral Fly and Tick Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Fly and Tick Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Fly and Tick Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact or allow others to contact treated animals until their coats are dry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Fly and Tick Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

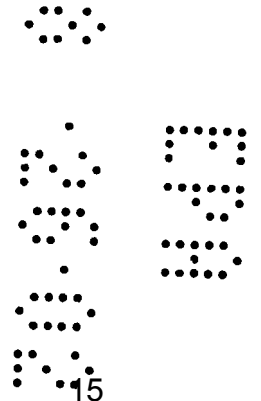


(Side Panel)

APPLICATION RATES

DO NOT APPLY MORE THAN 4 QUARTS OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.



(Side Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
	Ticks	4	10	Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Continued)

Reason to Issue: Amend text as per SRRD
Review Letter (8/21/01) and
PR Notice 2001-1

Date: 08/20/02
Supersedes: 1/16/98
Page 8 of 9

(Side Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Do not allow to freeze. Keep from extreme heat.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

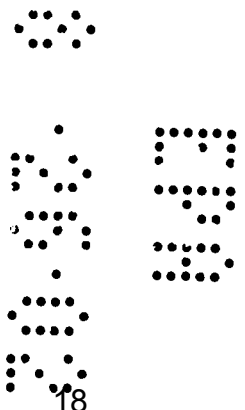
CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Reason to Issue: Amend text as per SRRD
Review Letter (8/21/01) and
PR Notice 2001-1

Date: 08/20/02
Supersedes: 1/16/98
Page 9 of 9

(Side Panel)

CONDITIONS OF SALE: THE DIRECTIONS ON THIS LABEL WERE DETERMINED THROUGH RESEARCH TO BE APPROPRIATE FOR THE CORRECT USE OF THIS PRODUCT. THIS PRODUCT HAS BEEN TESTED UNDER DIFFERENT ENVIRONMENTAL CONDITIONS BOTH INDOORS AND OUTDOORS SIMILAR TO THOSE THAT ARE ORDINARY AND CUSTOMARY WHERE THE PRODUCT IS TO BE USED. INSUFFICIENT CONTROL OF PESTS OR PLANT INJURY MAY RESULT FROM THE OCCURRENCE OF EXTRAORDINARY OR UNUSUAL CONDITIONS, OR FROM FAILURE TO FOLLOW LABEL DIRECTIONS. IN ADDITION, FAILURE TO FOLLOW LABEL DIRECTIONS MAY CAUSE INJURY TO ANIMALS, MAN, AND DAMAGE TO THE ENVIRONMENT. BAYER OFFERS, AND THE BUYER ACCEPTS AND USES, THIS PRODUCT SUBJECT TO THE CONDITIONS THAT EXTRAORDINARY OR UNUSUAL ENVIRONMENTAL CONDITIONS, OR FAILURE TO FOLLOW LABEL DIRECTIONS ARE BEYOND THE CONTROL OF BAYER AND ARE, THEREFORE, THE RESPONSIBILITY OF THE BUYER.





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

279621

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly & Tick Spray	PM# 03	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Agriculture Div., Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

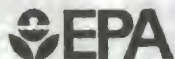
Attached to this application are five (5) copies of the revised label for Co-Ral Fly & Tick Spray (EPA Reg. No. 11556-115). The label was revised in accordance with the SRRD letter dated August 21, 2001 (copy attached). No other changes have been made to the labeling or the Confidential Statement of Formula for this product. Bayer understands it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands that if these changes are not consistent with the Agency's requirements set forth in the SRRD letter (8/21/01) and 40 CFR 156.10, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name F. Terry McNamara		Title Director, Preclin Dev & EPA Reg Affairs		Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Director, Preclinical Development & EPA Reg Affairs			
4. Typed Name F. Terry McNamara		5. Date 8/23/02			



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

279621

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

279621

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM# 0	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
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Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

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2. Signature	3. Title	
4. Typed Name	5. Date	

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5. Three copies of any data submitted;
6. Authorization letter where applicable;
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2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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- 1-5. Self-explanatory.
6. EPA Use Only.

A

Agriculture Division

August 23, 2002

Animal Health

Ms. Linda DeLuise
7505C
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 204060

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 268-2000

Subject: Revised labels for coumaphos products
EPA Reg. No.'s 11556-4, -11, -14, -23, -98, and -115

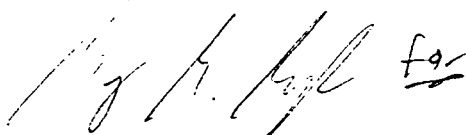
Dear Ms. DeLuise:

Attached are (5) text copies the revised label for Co-Ral Animal Insecticide 1% Shaker Can (EPA Reg. No. 11556-4), Coumaphos Technical (EPA Reg. No. 11556-11), Co-Ral Animal Insecticide 1% Bulk Dust (EPA Reg. No. 11556-14), Co-Ral Emulsifiable Livestock Insecticide (EPA Reg. No. 11556-23), Co-Ral Flowable Insecticide (EPA Reg. No. 11556-98), and Co-Ral Fly & Tick Spray (EPA Reg. No. 11556-115).

These labels were revised in accordance with the Agency letters dated August 21, 2001 (for all six products) and the SRRD memorandums dated February 14, 2001 (for 11556-4), March 2, 2001 (for 11556-11), February 21, 2001 (for 11556-14), March 1, 2001 (for 11556-23), March 1, 2001 (for 11556-98), and March 2, 2001 (for 11556-115). The letters and memos are attached to their respective application. No other changes or revisions were made to the labels other than the ones listed in Agency letter and SRRD memo.

Please call me at 913-268-2588 or Greg Gagliano at 913-268-2751 if you have any questions or need additional information.

Sincerely,



F. Terry McNamara
Director, Preclinical Development and EPA Regulatory Affairs

FTM:GGG/lt

Enclosures

Federal Express 08/23/02

Document Processing Desk (AMEND)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Enclosure: Letter to Ms. Linda DeLuise (7505C)

Application for Pesticide Amendment –

Co-Ral Animal Insecticide 1% Shaker Can (EPA Reg. No. 11556-4) -
five copies draft labeling & one copy EPA Letter dated Aug. 21,
2001, & one copy SRRD Memo dated Feb. 14, 2001

Application for Pesticide Amendment –

Coumaphos Technical (EPA Reg. No. 11556-11) -
five copies draft labeling & one copy EPA Letter dated Aug. 21,
2001, & one copy SRRD Memo dated March 2, 2001

Application for Pesticide Amendment –

Co-Ral Animal Insecticide 1% Bulk Dust (EPA Reg. No. 11556-14) -
five copies draft labeling & one copy EPA Letter dated Aug. 21,
2001, & one copy SRRD Memo dated Feb. 21, 2001

Application for Pesticide Amendment –

Co-Ral Emulsifiable Livestock Insecticide (EPA Reg. No. 11556-23)-
five copies draft labeling & one copy EPA Letter dated Aug. 21,
2001, & one copy SRRD Memo dated Mar. 1, 2001

Application for Pesticide Amendment –

Co-Ral Flowable Insecticide (EPA Reg. No. 11556-98) -
five copies draft labeling & one copy EPA Letter dated Aug. 21,
2001, & one copy SRRD Memo dated Mar. 1, 2001

Application for Pesticide Amendment –

Co-Ral Fly & Tick Spray (EPA Reg. No. 11556-115) -
five copies draft labeling & one copy EPA Letter dated Aug. 21,
2001, & one copy SRRD Memo dated Mar. 2, 2001

PESTICIDE REGISTRATION ACTION TRACKING SYSTEM
CODING FORM

INPROCESSING INFORMATION

Submission Bar Code: 5621241 ID Number: 11556-115 Action Code: 656

PM Team: 03 Reviewer: L. Deluise Due Date: 12/24/02

Date on Application: 8/23/02

EPA Received Date: 8/26/02

PM Received Date: 9/5/02

Chemical Code (1): _____ Chemical _____

Chemical Code (2): _____ Chemical _____

Proposed Use: _____

Description of Action: response to Agency ltr dated 8/21/2001

Related Actions: _____

OUTPROCESSING INFORMATION

Response Code: _____ Response Date: ____/____/____

75-Day Response:	Yes _____	No _____	MOS: (1) Cite All
CRP:	Yes _____	No _____	(4) Not Applicable
Restricted Use	Yes _____	No _____	(8) Selective
Exclusive Use:	Yes _____	No _____	
Manufacturing Use:	Yes _____	No _____	

Conditional Registration: Data Required

Guideline No. _____ Due Date: ____/____/____

Guideline No. _____ Due Date: ____/____/____

Comments:

656-LD

6-products

G. LARocca
9/5/02

FRONT END PROCESSING APPLICATION INFORMATION CHECK LIST

PM 03

EPA COMPANT NUMBER 11556-115

EPA REGISTRATION NUMBER STATUS ACTIVE ☒ CANCELLED ☐
(FOR AMENDMENTS)

NOT IN REFS ☐

"ME-TOO" CITED PRODUCT STATUS ACTIVE ☐ CANCELLED ☐

NOT IN REFS ☐

OPP# 279621 DATE 8-29-02

APPLICATION FOR AMENDMENT

WITH DATA		NO DATA	
INIT.	DATE	INIT.	DATE
FEU _____	_____	FEU <u>FW.</u>	<u>8-29-02</u>
SIG (DATA) _____	_____	PM <u>03</u>	
PM _____	_____	OPP # <u>279621</u>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

08/29/2002

F.T. MCNAMARA
BAYER CORP
P.O. BOX 390
SHAWNEE MISSION KS 662010390

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: CO-RAL FLY & TICK SPRAY
COMPANY NAME: BAYER CORP
OPP IDENTIFICATION NUMBER: 279621
EPA REGISTRATION NUMBER: 11556-115
EPA RECEIPT DATE: 08/26/2002

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Insecticide Branch, Product Manager 03, at (703) 305-6891.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly & Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Agriculture Div., Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>NOTIFICATION</u> Product Name <u>FEB 14 2002</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see attached explanation.

Basic CSF dated 1/9/2002

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

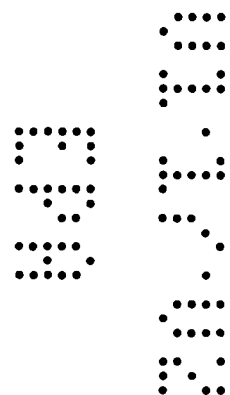
Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name F. Terry McNamara		Title Director, Preclin Dev & EPA Reg Affairs		Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>F. Terry McNamara</i>		3. Title Director, Preclinical Development & EPA Regulatory Affairs			
4. Typed Name F. Terry McNamara		5. Date 1/14/02			

Product ingredient source information may be entitled to confidential treatment

Attachment for Application for Pesticide Registration
Co-Ral[®] Fly and Tick Spray, EPA Reg. No. 11556-115

Enclosed with this application are two (2) copies of the revised Confidential Statement of Formula (CSF) for Bayer's Co-Ral[®] Fly and Tick Spray product (EPA Reg. No. 11556-115). The revision is being made by Notification as per PR Notice 98-10 which allows for a change in source for inert ingredients. Specifically, Bayer is changing the source of one inert ingredient from [REDACTED] [REDACTED] No other changes have been made to the CSF.



AUG 22 2002

Mr. F.T. McNamara
Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Submission of Label in accordance with the
Coumaphos Reregistration Eligibility Decision (RED)
document, and issuance of Unconditional Registration.
Product Name: CO-RAL Fly and Tick Spray
EPA Registration Number: 11556-115

On August 21, 2001 the Agency sent you a letter requesting
that you update your label and respond within thirty (30) days.
The Agency has not yet received your response.

Please submit you updated label within thirty (30) days. A
copy of the August 21, 2001 letter is included for your
convenience.

If you have any questions please call Linda A. DeLuise at
703 305-5428.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

AUG 21 2001

Mr. F.T. McNamara
Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Submission of Label in accordance with the
Coumaphos Reregistration Eligibility Decision (RED)
document, and issuance of Unconditional Registration.
Product Name: CO-RAL Fly and Tick Spray
EPA Registration Number: 11556-115
Submission Dated: January 10 and January 19, 2001

Your application for reregistration of the subject pesticide product under FIFRA sec. 3(c)(5) is provisionally acceptable. Submit three final printed copies of the proposed labeling incorporating the following revisions:

1. Incorporate any label revisions and/or approved amendments since the date of Bayer's original reregistration submission.
2. Incorporate all of the comments identified in the enclosed Agency Memorandum dated March 2, 2001 from the Special Review and Reregistration Division.

Please respond within thirty (30) days from the date of this letter stating your intentions to comply with the information/label requests cited above. This letter does not constitute registration or reregistration of CO-RAL Fly and Tick Spray, and such label claims may not be lawfully marketed until it is registered. Furthermore, the Agency will be unable to process any further label amendments, until all reregistration label issues are corrected, and an unconditional registration is issued.

To expedite handling, please return a copy of this letter with your finished labeling. If you have any questions please call Linda A. DeLuise at 703 305-5428.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosures



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

03/02/2001

MEMORANDUM:

Subject: Co-Ral Fly and Tick Spray
EPA Reg. No. 11556-115
Re: PRB Label Assessment

From: Maria Rivera Piansay, Chemist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Maria Rivera Piansay
03/06/01

Through Stephen Morrill
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

sm 3/6/2001

To: Arnold Layne
Product Manager 03
Registration Division (7505C)

BACKGROUND: Bayer Corporation has submitted 5 copies of draft labeling for the subject product in its 8 month response to the Coumaphos RED. PRB has completed a preliminary assessment of the draft labeling. In its assessment, PRB has considered the following: 1) Labeling requirements specified in the Coumaphos RED; 2) Labeling specified or required in the Product Chemistry and Acute Toxicity Reviews; and 3) Labeling requirements as specified in 40 CFR Part 156.10 and associated labeling policy documents such as the Label Review Manual or Pesticide Regulation Notices (PRNs). In addition, PRB has made recommendations that will improve the comprehension and consistency of all product labels. This document can be accessed electronically on the Lan through the Q:Drive in Word Perfect. The path is q:\rd\user\prb\label\011556\00115.

NOTE: This preliminary assessment contains recommendations intended to assist Product Managers in their final review of the pesticide label. Product Managers are encouraged to use all or portions of this assessment and then apply their own knowledge of the subject product and the product's regulatory history (including comparison with existing stamped accepted labeling) to conduct a final review of the label. It is the responsibility of the PM to attain the necessary label improvements required for final product reregistration.

SUMMARY OF FINDINGS:

I RED Risk Mitigation:

The subject product label contains risk mitigation labeling requirements as specified in the Coumaphos RED.

II Technical Review Requirements:

Product Chemistry: The subject product label contains the required labeling as specified in the product chemistry review dated 10/27/98.

Acute Toxicity: The subject product label does not contain the required labeling as specified in the acute toxicity review dated 08/06/99.

- The Hazards to Humans and Domestic Animals must be revised.

III Other Labeling Requirements:

The subject product does not contain the required labeling as specified by 40 CFR Part 156.10, PR Notices and the Label Review Manual.

- The company's phone number should be added to the label.
- The Hotline information should be added under First Aid.
- The Storage and Disposal text should be revised.
- Revisions are needed to the Warranty section.

Refer to Appendix 1 for more details and to Appendix II for suggested placement information.

RECOMMENDATIONS:

The subject product requires revisions to conform with the Technical Reviews (Acute Toxicity) and Agency label policies. Subject to final review by the Product Manager, PRB recommends that the registrant resubmit to the Product Manager, revised product labeling that addresses the deficiencies specified in this review and any other deficiencies specified by the Product Manager.

Refer to Appendix I.

PRB Label Analysis

Label Requirement	Acceptable	Not Acceptable	Comments/Recommendations
Restricted Use Pesticide	N/A		
Product Name	X		
Company Name and Information	X		PRB recommends the company's phone number be placed on the label. See Appendix II for suggested placement.
Identification Numbers	X		
Ingredients Statement	X		
Net Contents	X		
KOROC	X		
Signal Word	X		
Precautionary Statements			
Precautionary Statements Header	X		
First Aid	X		<p>The First Aid statements are correct, as per PR Notice 2001-1 and the acute toxicity review dated 08/06/99. However, the registrant should be encouraged to provide the following additional Hotline information on the label, as per PR notice 2001-1:</p> <p style="text-align: center;">"For additional information in case of emergency call toll free (Telephone Number)."</p> <p>Notes to PM: 1)The registrant should also be encouraged to place the First Aid statements in a box, as per PR Notice 2001-1. 2) Since the acute inhalation study is in category IV, no treatment statements are required. If the registrant wishes to place additional treatment statements on their label for this category, according to the LRM, it is acceptable.</p> <p>See Appendix II for formatting and suggested placement.</p>

Hazards to Humans and Domestic Animals		X	<p>As per the acute toxicity review dated 08/06/98, the HHDA statements must be modified as specified below:</p> <p>"May be fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing."</p> <p>Note to PM: If the registrant wishes to add an optional statement concerning inhalation, the statement should be placed in the end, as per the LRM (pages 8-7 and 8-16). The HHDA statements may be modified as follows: "May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing."</p>
PPE	X		
User Safety Requirements	X		
Engineering Controls	N/A		
User Safety Recommendations	X		
Environmental Hazards	X		See Appendix II for suggested placement.
Physical and Chemical Hazards	N/A		
Directions for Use (FIFRA Text, WPS and Storage and Disposal)			
Header "Directions for Use"	X		
Violation of Federal Law Text	X		
WPS Text	N/A		
Non- WPS Text	N/A		
Storage and Disposal	X		Per the Label Review Manual (page 13-1), PRB recommends that the heading "Storage" should be replaced with "Pesticide Storage."
Directions for Use (General Instructions and Information)			
General Instructions and Information Sub-Header	N/A		
Chemigation/Prohibition (if applicable)	N/A		
Spray Drift Labeling	N/A		

General Information (non-site specific information on uses, pests, mixing and loading, tank mixing, etc....)	N/A		
General Precautions and Restrictions	X		All restrictions required by the RED are on the label.
Directions for Use (Application Instructions)			
Application Instructions	X		The term "Recommended Applications" implies that the rates are recommendations only and thus, do not have to be followed. The registrant should be required to replace the heading with a more appropriate heading such as "Application Rates" or "Application Instructions".
Warranty Information			
Consistency with label instructions	X		
Not false and misleading		X	<p>The Limited Warranty and Limitation of Damages contains an overbroad statement concerning limitation of liability ("Any damages arising from a breach of this warranty, shall be limited to direct damages, and shall not include consequential commercial damages such as loss of profits or values, etc."). The registrant should be informed that such a statement may be misleading and may constitute misbranding under FIFRA. OGC has suggested that limitation of liability statements, such as the one cited above, be preceded by a qualifying phrase such as "To the extent allowable by State law, ..." or otherwise qualified in such a way as to make it clear that it is the registrant's intent that Bayer Corp.'s liability be limited and that the Limited Warranty and Limitation of Damages is not meant to be a statement of law. However, the guidance in Policy and Criteria Notice 2163.1, states that PM's will not, at this time, conduct a detailed review of such liability disclaimers, but will inform registrants that approval of the label with such statements should not be construed as a decision by the Agency that the language is not misleading and that the label might eventually have to be changed. Refer to Policy and Criteria Notice 2163.1 for further information.</p> <p>See Appendix II for suggested placement.</p>
General Comments			
None			

Appendix II

Suggested Presentation of Label

Product Name

Ingredients.....

EPA Registration and Establishment Numbers

Company Name, Address, Phone Number

Net Contents

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none">*Call poison control center or doctor immediately for treatment advice.*Have person sip a glass of water if able to swallow.*Do not induce vomiting unless told to do so by the poison control center or doctor.*Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">*Take off contaminated*Rinse skin immediately with plenty of water for 15-20 minutes.*Call a poison control center or doctor for treatment advice.
IF IN EYES	<ul style="list-style-type: none">*Hold eye open and rinse slowly and gently with water for 15-20 minutes.*Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.*Call a poison control center or doctor for treatment advice.
IF INHALED (optional statement)	<ul style="list-style-type: none">*Move person to fresh air.*If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.*Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
<p>"In case of emergency call toll free number XXXXX."</p> <p>"Have the product container or label with you when calling a poison control center or doctor or going for treatment."</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

PPE

User Safety Requirements

USER SAFETY RECOMMENDATIONS

ENVIRONMENTAL HAZARDS

DIRECTIONS FOR USE

It is a Violation of Federal Law.....

STORAGE AND DISPOSAL

General Information (non-site-specific)

General Precautions and Restrictions

APPLICATION INSTRUCTIONS (site-specific)

Application Instructions

WARRANTY STATEMENT

DATE OUT: 27/OCT/1998

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing Use [], End Use Product [x]
BARCODE No.: D244708 EPA RECEIVED DATE: 12/FEB/98 Reg./File Symbol No.: 11556-115
PRODUCT NAME: Co-Ral Fly and Tick Spray (LIS) MRIDs: 428745-01
COMPANY NAME: Bayer Corp. Action Code: 674

FROM:

Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508W)

Maria Rivera Piansay 10/28/98
of Eric M. Walsh
10/27/98

TO:

CP Moran, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508W)

INTRODUCTION:

With this submission, the registrant, Bayer Corp., provided a Confidential Statement of Formula (CSF), a basic formulation dated 28/JAN/98, a draft label received by the Agency on 12/FEB/98 and MRID number 428745-01 that contains the product chemistry data. The registrant is requesting FIFRA Sec. 4 reregistration of the end use product Co-Ral Fly and Tick Spray (LIS), EPA Reg. No. 11556-115.

FINDINGS:

1. A Reregistration Eligibility Decision (RED), Case # 0018, was issued Aug. 1, 1996 for the Technical Grade Active Ingredient (TGAI), Coumaphos, EPA Reg. No. 11556-11. No generic data gaps were cited.
2. The submitted product chemistry are adequate and support FIFRA Section 4 reregistration of this product.
3. This product is produced by a non-integrated formulation system, meaning that the technical source claimed on the label is registered. Co-Ral Fly and Tick Spray has a claimed label concentration of 6.15% 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl)phosphorothioate (Coumaphos) and 93.85% inert ingredients.
4. The submitted MRID # 428745-01 contains adequate enforcement analytical methods for the active ingredient Coumaphos. The methods used are: High Performance Liquid Chromatography using Bayer Animal Health Test Method TMC-2.57, dated 06/21/93 or Infrared Spectroscopy using Bayer Animal Health Test Method TMC-2.20, dated 06/21/93. These methods are adequate and satisfy the requirements of 40 CFR 158.180.
5. The registrant should be advised to correct the proposed upper and lower certified limits (for the active ingredient) on the CSF, from 6.8% and 5.5% to 6.46% and 5.84%, respectively, as per the regulations of 40 CFR 158.175. Other information presented in the CSF are acceptable and

support reregistration of this product.

6. All ingredients claimed on the CSF are cleared for use in pesticide formulations.
7. The ingredient statement, the physical/chemical hazard statement, and the storage and disposal statement cited on the product's label satisfy the requirements of 40 CFR156.10.

CONCLUSIONS:

Other than submitting a revised CSF (Finding 5 above), the registrant has satisfied product chemistry data requirements for Section 4 Reregistration of this product.

REVIEW OF PRODUCT CHEMISTRY DATA:**PRODUCT NAME:** Co-Ral Fly and Tick Spray (LIS) EPA Reg. No: 11556-115**Group A:** Series 830-Product Identity, Composition, and Analysis (40 CFR 158.155, .160, .165, .167, .170, .175 & .180).**830-1550 Product Identity and Composition**

Co-Ral Fly and Tick Spray is produced by a non-integrated formulation system using a technical grade active ingredient, Coumaphos (96% Chemical Purity), EPA Reg. No. 11556-11. A review of the calculations presented on the CSF indicate that the proposed upper and lower certified limits for the active ingredient, based on the nominal concentration, do not fall within the specified limits of 40 CFR 158.175(b)(2). The upper and lower certified limits should be $\pm 5\%$ of the nominal value. Thus, the correct upper and lower certified limits would be 6.46% and 5.84%, respectively, unless adequate explanation is presented as to why there must be wider certified limits.

830-1600 Description of Materials Used to Produce the Product

Refer to Confidential Appendix A.

830-1620 Discussion of Formulation Process

Refer to Confidential Appendix A.

830-1670 Discussion of Formation of Impurities

Refer to Confidential Appendix A.

830-1700 Preliminary Analysis

Refer to Confidential Appendix A

830-1750 Certified Limits

Refer to Confidential Appendix A.

830-1800 Enforcement of Analytical Method:

The analytical methods for the active ingredient in this product are presented in MRID # 428745-01, "Bayer Animal Health Test Method" TMC -2.57, an HPLC method that involves determination of the coumaphos concentration by UV detection, by comparison of the peak height of the sample with the peak height of a standard of known concentration.

An alternate method is "Bayer Animal Health Test Method" TMC-2.20, an infrared (IR) spectroscopic method which involves comparison of the infrared absorbances of the sample and the standard at the absorbance maximum near 1730 cm^{-1} .

Sample calculations and chromatograms have been provided and found to be adequate.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190):MRID Nos.: 428745-01, unless indicated

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830-	VALUE OR QUALITATIVE DESCRIPTION/ METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Waived, per PR Notice 92-5.
-6303 Physical State	Liquid.
-6304 Odor	Data waived per PR Notice 92-5.
-6314 Oxidation/Reduction: Chemical Incompatibility	Oxidized by KMnO_4 but not by NaOCl . Product was inactive toward reduction by metallic zinc
-6315 Flammability/Flame Extension	Flashpoint is greater than 195°C .
-6316 Explodability	Not required; product does not contain ingredients with any explosive potential.
-6317 Storage Stability of the Product	Data waived per PR Notice 92-5.
-6319 Miscibility	Not applicable; product is not intended to be diluted with petroleum distillates.
-6320 Corrosion Characteristics	Not required; active ingredient is a registered source.
-6321 Dielectric Breakdown Voltage	Not required; product will not be used around electrical equipments.
-7000 pH	6.3 at 20°C .
-7100 Viscosity	7.5 centipoise at 25°C .
-7300 Density/Relative Density/ Bulk Density	8.4 lb./gal.

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product

The raw materials for this product are listed on the CSF.

830-1650 Description of Formulation Process

MRID # 428745-01

[REDACTED]

830-1670 Discussion of Formation of Impurities

The registrant reported no reaction may be expected with any component during the formulation of this product, thus no impurities are formed.

830-1700 Preliminary Analysis

Not required for non-integrated products.

830-1750 Certified Limits

Coumaphos: Lower Limit: 5.84%; Nominal Conc.: 6.15%; Upper Limit: 6.46%

(The reported upper and lower certified limits of 6.8% and 5.5% should be changed to 6.46% and 5.84% as per the regulations of 40 CFR 158.175(b)(2)).

M.R. Piansay and Central File (EPA Reg. No. 11556-115).

7508W:SRRD:PRB:CS-1: M.R.P.: (27/OCT/98):703-308-8063:<11556-115>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 6, 1999

MEMORANDUM:

Subject: EPA Reg. No.: 11556-23/ CO-RAL® Emuslifiable Livestock Insecticide
DP Barcode: D258232
Case No.: 18

Subject: EPA Reg. No.: 11556-115/ CO-RAL® Fly and Tick Spray
DP Barcode: D258234
Case No.: 18

From: Ann Hanger, Environmental Protection Specialist *a. Hanger*
Product Reregistration Branch
Special Review and Reregistration Division (7508C) *MJP*

To: Barbara Briscoe, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

FORMULATION FROM EPA Reg. No.11556-23 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Coumaphos.....	11.60%
<u>Inert Ingredient(s):</u>	<u>88.40%</u>
Total	100.00%

FORMULATION FROM EPA Reg. No.11556-115 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Coumaphos.....	6.15%
<u>Inert Ingredient(s):</u>	<u>93.85%</u>
Total	100.00%

BACKGROUND: In a resubmission response to the review conducted on the 8 month response to the Coumaphos RED, the registrant has submitted MRID Nos. 448718-09 (acute dermal) and 448718-02 (acute inhalation) to address the deficiencies noted in the review by A. Hanger of PRB/SRRD dated September 14, 1998. EPA Reg. No. 11556-23 is in batch 3 and EPA Reg. No. 11556-115 is not addressed by the Coumaphos RED. However, EPA Reg. No. 11556-115 may be supported by the data performed on EPA Reg. No. 11556-23.

RECOMMENDATIONS:

- In the acute dermal study, the test material was applied directly to the gauze rather than the skin of the test animal. However, this deviation is not considered to affect the test results.
- The submitted acute dermal and acute inhalation studies conducted on EPA Reg. No. 11556-23 are acceptable.
- The request for EPA Reg. No. 11556-115 to be supported by the acute dermal and acute inhalation studies submitted for EPA Reg. No. 11556-23 is acceptable.

The acute toxicity guidelines for EPA Reg. No. 11556-23 and 11556-115 are satisfied.

The acute toxicity profile for EPA Reg. Nos. 11556-23:

Acute Oral	I	Acceptable
Acute Dermal	III	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye	III	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization	skin-sensitizer	Self Validated

The acute toxicity profile for EPA Reg. Nos. 11556-115:

Acute Oral	II	Acceptable
Acute Dermal	III	Cited
Acute Inhalation	IV	Cited
Primary Eye	III	Cited
Primary Dermal	IV	Cited
Skin Sensitization	skin-sensitizer	Cited

PRECAUTIONARY LABELING

ID #: 011556-00023 CO-RAL (COUMAPHOS) EMULSIFIABLE LIVESTOCK INSECTICIDE

RESTRICTED USE CLASSIFICATION RECOMMENDED:

Due to acute oral toxicity category.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

INGREDIENT LABELING:

Contains Petroleum Distillate.

SIGNAL WORD: DANGER PELIGRO

POISON (SKULL and CROSSBONES symbol)

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear long-sleeved shirt and long pants, socks and shoes and chemical resistant gloves (such as Barrier Laminate or Viton). Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

FIRST AID:

IF SWALLOWED*: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5

minutes, then continue rinsing. Call a poison control center or doctor for treatment advise.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN:

The proposed label must contain the following guidance:

"Note to Physician: This product may pose an aspiration pneumonia hazard. Contains petroleum distillate."

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician" which addresses the presence of a cholinesterase inhibitor and category I acute oral toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

*First aid statement for acute oral toxicity must appear on the front panel.

PRECAUTIONARY LABELING

ID #: 011556-00115 CO-RAL LIVESTOCK INSECTICIDE SPRAY

INGREDIENT LABELING:

Contains Petroleum Distillate.

SIGNAL WORD: WARNING AVISO

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

May be fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear long-sleeved shirt and long pants, socks and shoes and chemical resistant gloves (such as Barrier Laminate or Viton). Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

FIRST AID:

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN:

The proposed label must contain the following guidance:

"Note to Physician: This product may pose an aspiration pneumonia hazard. Contains petroleum distillate."

Note to PM/CRM/Registrant: The proposed label should contain a "Note

to Physician" which addresses the presence of a cholinesterase inhibitor. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: Arnold Layne, 03
MRID No.: 448718-09

Reviewer: Ann Hanger
Study Completion Date: July 1, 1999
Study No.: 99-A22-AU

Testing Facility: Bayer Corporation
Author: Sturdivant, D.W.
Quality Assurance (40 CFR §160.12): Included

Test Material: Coumaphos (CO-RAL® Emulsifiable Livestock Insecticide, 12.1% Coumaphos); Lot 416166; dark brown liquid

Species: Rats; Wistar Hannover

Age: Young adult

Weight: Males: 229-301 g; Females: 170-211 g

Source: Charles River Laboratories, Raleigh, NC

Dermal LD₅₀ Testing:

Conclusion:

- LD₅₀ (mg/kg):**
Males: > 2000 mg/kg
Females: > 2000 mg/kg
Combined: > 2000 mg/kg
- The estimated LD₅₀ is** > 2000 mg/kg
- Tox. Category:** III **Classification:** Acceptable

Procedure (Deviations from §81-2): Test material was applied directly to gauze rather than the skin of the test animal. However, this is not considered to affect the test results.

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
500	0/6	0/6	0/12
1000	0/6	0/6	0/12
2000	0/6	0/6	0/12

Observations: Compound related signs included muscle fasciculations (females), urine staining (both) and nasal staining (males).

Gross Necropsy: Compound related gross lesions were not evident at necropsy.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Arnold Layne, 03
MRID No.: 448718-02

Reviewer: Ann Hanger
Study Completion Date: June 14, 1999
Study No.: T5068290

Testing Facility: Bayer Ag
Author: Pauluhn

Quality Assurance (40 CFR §160.12): Included

Test Material: Coumaphos (CO-RAL® Emulsifiable Livestock Insecticide; 12.2% Coumaphos); Lot 416166; brown, translucent liquid

Species: Rats; SPF bred Wistar rats

Age: Young adult

Weight: Males: 199-301 g; Females: 168-224 g

Source: Harlan-Winkelmann GmbH, Borcheln (Germany)

Conclusion:

1. **LC₅₀ (mg/L):**
Males: >2.42 mg/L
Females: >2.42 mg/L
2. **The estimated LC₅₀ is** >2.42 mg/L
3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviations from §81-3): The relative humidity should be between 30 and 70%. However, this is not considered to have an affect on the test results.

Exposure Concentration mg/L (Analytically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
0.915	0/5	0/5	0/10
1.585	0/5	1/5	1/10
2.420	0/5	2/5	2/10
5.050	5/5	5/5	10/10

Clinical Observations: Exposure to 2.420 and 0.915 mg/L did not result in mortality in males and females, respectively. The concentration-mortality relationship suggests that females are more susceptible than males. The following clinical signs were observed: motility reduced, prostration (lying on belly), piloerection, ungroomed hair-coat, labored breathing pattern, bradypnea, sneezing, limp, tremor, fasciculations, emaciation, miosis, cyanosis, salivation, nostrils: red encrustations, hypothermia, decreased reflexes and decreased body weights. All signs resolved within the first half of the second postexposure week.

Gross Necropsy Findings: Necropsy findings were unobtrusive in surviving rats. Rats that succumbed displayed less collapsed lungs and secretions in airways.

Chamber Atmosphere		
Analytical conc. (mg/L)	MMAD (μm)	GSD
0.915	1.85 & 1.65	2.31 & 1.94
1.585	1.91 & 1.88	2.20 & 2.19
2.420	2.04 & 1.85	2.19 & 1.88
5.050	2.16 & 2.11	2.11 & 2.07

Other Information: Approximately 67-82% of particles had an aerodynamic diameter $<3 \mu\text{m}$.

Chamber Environment ^a	
Chamber Volume	3.8 L
Airflow	15 LPM
Temperature	20°C
Relative Humidity	2.9-32.4%

^a nose only

ACUTE TOX ONE-LINERS

1. REGISTRATION NO.: 11556-23
2. PC CODE: 036501
3. CURRENT DATE: September 14, 1998
4. TEST MATERIAL: Coumaphos (CO-RAL® Emulsifiable Livestock Insecticide)
Coumaphos 12%

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute dermal toxicity rat/ Bayer Corp/ 99-A22-AU/ 01-JUL-1999	448718-09	LD ₅₀ > 2000 mg/kg (males, females, combined)	III	A
Acute inhalation toxicity rat/ Bayer Ag/ T5068290/ 14- JUN-1999	448718-02	LC ₅₀ > 2.420 mg/L	IV	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

275007

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly & Tick Spray	PM# 03	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Agriculture Div., Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The CSF was revised in accordance with the Agency request dated January 11, 2001 (letter attached).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name F. Terry McNamara		Title Manager, Preclinical Development		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					6. Date Application Received (Stamped)
2. Signature F. Terry McNamara		3. Title Manager, Preclinical Development			
4. Typed Name F. Terry McNamara		5. Date 1/19/01			



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

275007

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name		Title	
		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature		3. Title	
4. Typed Name		5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

275007

Application for Pesticide - Section I

1. Company/Product Number

2. EPA Product Manager

3. Proposed Classification

4. Company/Product (Name)

PM#

☐ None ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(II), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

☐ Check if this is a new address

Section - II

☐ Amendment - Explain below.

☐ Final printed labels in response to Agency letter dated _____

☐ Resubmission in response to Agency letter dated _____

☐ "Me Too" Application.

☐ Notification - Explain below.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes
☐ No

Unit Packaging

☐ Yes
☐ No

Water Soluble Packaging

☐ Yes
☐ No

2. Type of Container

☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____

* Certification must be submitted

If "Yes" Unit Packaging wgt.

No. per container

If "Yes" Package wgt

No. per container

Location of Net Contents Information

☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐ On Label
☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph
☐ Paper glued
☐ Stenciled

☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name

Title

Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

(Stamped)

2. Signature

3. Title

4. Typed Name

5. Date

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2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
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- 1-5. Self-explanatory.
6. EPA Use Only.

George
Larocca
1/25/01



Agriculture Division

Animal Health

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone 913 268-2000

Via Federal Express

January 22, 2001

Ms. Linda DeLuise (7505C)

Document Processing Desk (AMEND)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: CSF changes as per DERs

Dear Ms. DeLuise:

Attached please find the amendment applications for CSF changes to Bayer's currently registered coumaphos products. Specifically, these products are:

Co-Ral Insecticide 1% Bulk Dust (EPA Reg. No. 11556-14)
Co-Ral Insecticide 1% Shaker Can (EPA Reg. No. 11556-4)
Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115)

The enclosed draft CSFs (2 copies of each) incorporate the changes required by and specified in the Agency reviews received by Bayer from SRRD (see letters dated January 11, 2001 attached to each application).

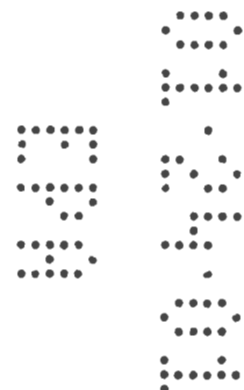
Please call me at 913-268-2588 or Mr. Greg Gagliano at 913-268-2751 if you have any questions or need additional information.

Sincerely,

F. Terry McNamara
F. Terry McNamara
Manager, Preclinical Development

cc: Moana Appleyard, 7508C (letter only)

x:moiij/letters/ggg0169.doc



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 11 2001

CERTIFIED MAIL:

F.T. McNamara
Manager, Preclinical Development
Bayer Corporation
Agricultural Division, Animal Health
9009 West 67th Street, Bldg. 1
Merriam, KS 66202

Subject: Coumaphos Product Reregistration

Dear Mr. McNamara:

Enclosed is the product chemistry review for CO-RAL, Fly and Tick Spray, EPA Reg. No. 11556-115. Other than submitting a revised CSF for this product, the product chemistry requirements are satisfied. Please correct the following information:

- ▶ change the proposed upper and lower certified limits for the active ingredient on the CSF, from 6.8% and 5.5% to 6.46% and 5.84%, respectively.

Please submit the required information within 10 days of receipt of this letter. Failure to submit the information within the specified time frame, may result in a Notice of Intent to Suspend Bayer's product registration. Please contact Moana Appleyard at 703 308-8175 if you have any questions.

Sincerely,

Linda S. Propst, Chief
Planning and Reregistration Branch
Special Review and Reregistration Division

Enclosure

		CONCURRENCES					
SYMBOL	7508C	7508C					
SURNAME	M. Anderson	Propst					
DATE	11/6/00	1/8/01					

Z 294 080 777

US Postal Service

Receipt for Certified Mail

No Insurance Coverage Provided.

Do not use for International Mail (*See reverse*)

Sent to

Mr. Terry McNamara

Street & Number

P.O.Box 390

Post Office, State, & ZIP Code

Shawnee Mission, KS 66201-

Postage

\$

0390

Certified Fee

Special Delivery Fee

Restricted Delivery Fee

Return Receipt Showing to Whom & Date Delivered

Return Receipt Showing to Whom, Date, & Addressee's Address

TOTAL Postage & Fees

\$

Postmark or Date

64

Stick postage stamps to article to cover First-Class postage, certified mail fee, and charges for any selected optional services (*See front*).

1. If you want this receipt postmarked, stick the gummed stub to the right of the return address leaving the receipt attached, and present the article at a post office service window or hand it to your rural carrier (*no extra charge*).

2. If you do not want this receipt postmarked, stick the gummed stub to the right of the return address of the article, date, detach, and retain the receipt, and mail the article.

3. If you want a return receipt, write the certified mail number and your name and address on a return receipt card, Form 3811, and attach it to the front of the article by means of the gummed ends if space permits. Otherwise, affix to back of article. Endorse front of article **RETURN RECEIPT REQUESTED** adjacent to the number.

4. If you want delivery restricted to the addressee, or to an authorized agent of the addressee, endorse **RESTRICTED DELIVERY** on the front of the article.

5. Enter fees for the services requested in the appropriate spaces on the front of this receipt. If return receipt is requested, check the applicable blocks in item 1 of Form 3811.

6. Save this receipt and present it if you make an inquiry.

65
102520-99-M-0079

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 11 2001

CERTIFIED MAIL:

Mr. Terry McNamara
Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS
66201-0390

Subject: Reviews for Coumaphos Products

Dear Mr. McNamara:

Enclosed are the acute toxicology and product chemistry reviews for Bayer's coumaphos products. Accept for a few minor corrections on the CSF's of products 11556-115 and 11556-4, Bayer has satisfied the data requirements for Coumaphos product reregistration. Please submit the revised CSF's within 20 days of receipt of this letter. Failure to submit the data within the specified time frame may lead to a Notice of Intent to Suspend Bayers product registrations. Please contact Moana Appleyard at (703)308-8175 if you have questions.

Sincerely,

Linda S. Propst, Chief
Product Reregistration Branch
Special Review and Reregistration

Enclosures

CONCURRENCES							
SYMBOL	75081	7508C					
SURNAME	M. Appleyard	L. Propst					
DATE	12/21/00	1/9/01					

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY
*U.S. Government Printing Office: 1992 — 620-856/40672

Reason to Issue: Amend text as per RED
Addendum and PR Notice 2001-1

Date: 01/09/01
Supersedes: 1/16/98
Page 1 of 9

(Front Panel)

Co-Ral®

(coumaphos)

FLY AND TICK SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
Inert Ingredients*:	93.85%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

KEEP OUT OF REACH OF CHILDREN

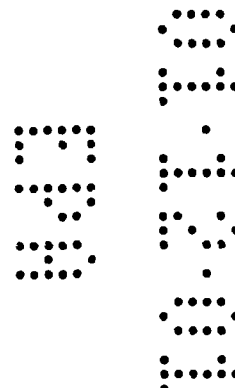
WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes.

**SEE BACK AND SIDE PANELS FOR FIRST AID
AND OTHER PRECAUTIONARY STATEMENTS**

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.



(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are barrier laminate and viton (≥ 14 mils). If you want more options, follow the instructions for Category G on an EPA chemical-resistance category selection chart.

Mixers, loaders, and others exposed to the concentrate (such as during a spill or equipment breakdown) must wear long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron, and face shield or goggles.

Applicators and all other handlers exposed to the diluted product must wear long-sleeve shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from the other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

(Side Panel)

FIRST AID

Contains an organophosphate that inhibits cholinesterase.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed - Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

If inhaled - Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

If on skin or clothing - Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

If in eyes - Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Note To Physician - Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine. Contains petroleum distillate - vomiting may cause aspiration pneumonia.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, birds, fish and aquatic invertebrates. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

(Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

APPLICATION RESTRICTIONS

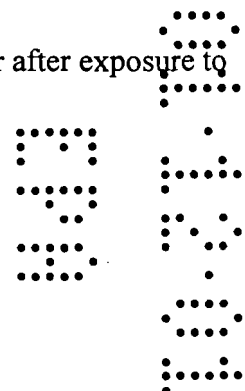
For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Fly and Tick Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.



(Side Panel)

Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.

Entry Restriction: Do not contact or allow others to contact treated animals until their coats are dry.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

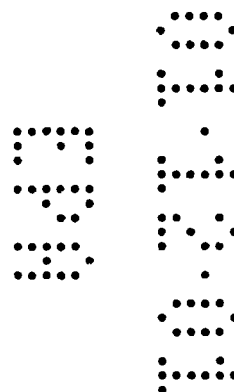
Co-Ral Fly and Tick Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Fly and Tick Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Fly and Tick Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

(Side Panel)

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Fly and Tick Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.



(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
	Ticks	4	10	Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly & Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Agriculture Div., Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The label was revised in accordance with the RED Addendum and PR Notice 2001-1. See attached explanation.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name F. Terry McNamara		Title Manager, Preclinical Development		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Manager, Preclinical Development			
4. Typed Name F. Terry McNamara		5. Date 01/10/01			

ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDMENT

Enclosed for Agency acceptance are five (5) copies each of the draft label, dated January 9, 2001, for Co-Ral Fly and Tick Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is based on the label which the Agency accepted on February 19, 1998.

The proposed changes to the Co-Ral Fly and Tick Spray label are based on the RED Addendum (EPA 738-R-00-010) which mandates certain changes in text and PR Notice 2001-1 which requests voluntary changes to the First Aid statement.

Specifically, the following are the changes made to the existing EPA-accepted labeling:

- 1) Previous labeling contained the First Aid statement:

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Repeat until vomit fluid is clear. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with of soap and water. Get medical attention if irritation appears.

If in eyes: Flush with plenty of water. Call physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

With the enclosed draft labeling, Bayer proposes to change the First Aid statement to the exact wording used in PR Notice 2001-1:

FIRST AID

Contains an organophosphate that inhibits cholinesterase.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed - Immediately call poison control center or doctor. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

If inhaled - Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

If on skin or clothing - Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

If in eyes - Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Note to Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine. Contains petroleum distillate – vomiting may cause aspiration pneumonia.

2) Previous labeling contained the following protective equipment statement:

Applicators and handlers exposed to the concentrate or participating in spray operations must wear long sleeve shirt, long pants; chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, chemical-resistant footwear plus socks, chemical resistant apron, face shield or goggles. All other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, chemical-resistant footwear plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Follow manufacturer's instructions for cleaning/maintaining personal protective

equipment. If no such instructions for washables exist, use detergent and hot water. Keep and wash personal protective equipment separately from the other laundry

As specified in the RED Addendum, the Protective Clothing Statement in previous labeling was deleted and replaced by a new statement, entitled "Personal Protective Equipment". The new section uses the exact wording as specified in the RED Addendum and was added under the Hazards to Humans and Domestic Animals statement as follows:

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are barrier laminate and viton (≥ 14 mils). If you want more options, follow the instructions for Category G on an EPA chemical-resistance category selection chart.

Mixers, loaders, and others exposed to the concentrate (such as during a spill or equipment breakdown) must wear long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron, and face shield or goggles.

Applicators and all other handlers exposed to the diluted product must wear long-sleeve shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from the other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

3) Previous labeling contained the following Environmental Hazards statement:

"This pesticide is toxic to birds, fish and aquatic invertebrates."

With the enclosed draft labeling, Bayer proposes to change the Environmental Hazards statement with the exact wording specified in the RED Addendum:

“This pesticide is toxic to mammals, birds, fish and aquatic invertebrates.”

The sentence “Do not apply directly to any body of water” was deleted from the Environmental Hazards statement as specified in the RED Addendum.

4) Previous labeling contained the following Entry Restriction statement:

“Do not contact treated animals until their coats are dry.”

With the enclosed draft labeling, Bayer proposes to change the statement with the exact wording specified in the RED Addendum:

“Do not contact or allow others to contact treated animals until their coats are dry.”

5) As specified in the RED Addendum, the Use Restrictions statement in previous labeling was re-titled “Application Restrictions” and moved from the middle of the Direction for Use section to the beginning of the Directions for Use section. In addition, the Premise Precaution statements located at the end of the Environmental Hazards section in previous labeling were incorporated into the “Application Restrictions” section as specified by the RED Addendum.

As the proposed modifications in the enclosed labeling were Agency requested, and as none of the proposed changes require data review, we anticipate ready Agency acceptance of the proposed labeling.

via Federal Express 1/29/98

Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

cc: Mr. George T. LaRocca
Ms. Linda DeLuise

bc: R. G. Arther
C. L. Basel
D. D. Cox
L. Fought
G. G. Gagliano
R. Henry
T. R. Lenz
F. T. McNamara
A. Pishny
J. Rueter
Reg. Book

Attachments: • Application for Pesticide Amendment (OPP #251090)
• Labeling Co-Ral® (coumaphos) Fly and Tick Spray
(EPA Reg. No. 11556-115) - 5 copies
• Confidential Statement of Formula



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251090

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>	3. Title Manager, Preclinical Development		
4. Typed Name F. T. McNamara	5. Date 1/26/98		

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address BAYER CORP AGRICULTURE DIVISION, ANIMAL HEALTH BOX 390 SHAWNEE MISSION KS 66201		2. Case # and Name 0018 Coumaphos		3. Date and Type of DCI PRODUCT SPECIFIC 04 22 1997	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
11556-115		N.A.	N.A.		X
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <i>F. T. McNamara</i>				9. Date 3/3/97	
10. Name of Company Contact F. T. McNamara, Manager, Biochemistry and Pesticide Registrations				11. Phone Number (913) 268-2588	

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address BAYER CORP AGRICULTURE DIVISION, ANIMAL HEALTH BOX 390 SHAWNEE MISSION KS 66201	2. Case # and Name 0018 Coumaphos EPA Reg. No. 11556-115	3. Date and Type of DCI PRODUCT SPECIFIC ID# 11556-RD-5739
---	--	--

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
			1	2	3				
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
61-2(b)	Discussion of formation of (1,3) impurities					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
63-7	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
63-12	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
63-15	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6
63-16	Explosibility (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	Option 6

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <i>F. T. McNamara</i>	11. Date 3/3/97
12. Name of Company Contact F. T. McNamara, Manager, Biochemistry and Pesticide Registrations	13. Phone Number (913) 268-2588

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address

BAYER CORP
AGRICULTURE DIVISION, ANIMAL HEALTH
BOX 390
SHAWNEE MISSION KS 66201

2. Case # and Name

0018 Coumaphos

EPA Reg. No. 11556-115

3. Date and Type of DCI

PRODUCT SPECIFIC
ID# 11556-RD-5739

NOV 22 1997

4. Guideline Requirement Number	5. Study Title	6. Use Pattern	Progress Reports			7. Test Substance	8. Time Frame	9. Registrant Response
			1	2	3			
63-17	Storage stability (18)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
63-18	Viscosity (13)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
63-19	Miscibility (14)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
63-20	Corrosion characteristics	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
63-21	Dielectric breakdown voltage (15)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
	<u>Acute Toxic - Regular Chemical</u>							
81-1	Acute oral toxicity-rat (1,36,37)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
81-2	Acute dermal toxicity-rabbit/rat (1,2,37)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
81-3	Acute inhalation toxicity-rat (3)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
81-4	Primary eye irritation-rabbit (2)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
81-5	Primary dermal irritation (1,2)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6
81-6	Dermal sensitization (4)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	Option 6

Initial to indicate certification as to information on this page
(full text of certification is on page one).

FTM

Date

3/3/97

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0018 Coumaphos

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackaging of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGA1 = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

- 1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
- 2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
- 3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
- 4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
- 5 Certified limits are not required for inert ingredients in products proposed for experimental use.
- 9 Required if test substances are dispersible with water.
- 10 Required if product contains an oxidizing or reducing agent.
- 11 Required if product contains combustible liquids.
- 12 Required if product is potentially explosive.
- 13 Required if product is a liquid.
- 14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
- 15 Required if end-use product is liquid and is to be used around electrical equipment.
- 18 Required for MP and EP but should not be submitted for EP unless (a) efficacy data are required to be submitted, (b) the storage stability data show that the active ingredient(s) is (are) not within the certified limits or toxicologically significant degradates are detected, or (c) product instability is suspected or incidents of instability are reported. Refer to PR Notice 92-5 for more information.

Acute Toxic - Regular Chemical

- 1 Not required if test material is a gas or highly volatile.
- 2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.

FTM 3/3/97

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0018 Coumaphos

Footnotes (cont.):

- 3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
- 4 Required unless repeated dermal exposure does not occur under conditions of use.
- 36 Special testing (acute, subchronic, and/or chronic) is required for organophosphates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.
- 37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

843

254 2

FTM 3/3/97

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">EPA REGISTRATION NO. 11556-115</td> <td style="width: 50%;">DATE OF ISSUANCE III 21 1991</td> </tr> <tr> <td colspan="2">TERM OF ISSUANCE Until Reregistration</td> </tr> <tr> <td colspan="2">NAME OF PESTICIDE PRODUCT Co-Ral Livestock Insecticide Spray</td> </tr> </table>	EPA REGISTRATION NO. 11556-115	DATE OF ISSUANCE III 21 1991	TERM OF ISSUANCE Until Reregistration		NAME OF PESTICIDE PRODUCT Co-Ral Livestock Insecticide Spray					
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NAME OF PESTICIDE PRODUCT Co-Ral Livestock Insecticide Spray											
NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: center;">MILES A. H. / R & D</td> </tr> <tr> <td style="width: 50%;">Rec'd 7/22/94</td> <td style="width: 50%;"></td> </tr> <tr> <td>Action Copy To _____</td> <td></td> </tr> <tr> <td>Replied _____</td> <td></td> </tr> <tr> <td>Info Copies To _____</td> <td></td> </tr> </table>	MILES A. H. / R & D		Rec'd 7/22/94		Action Copy To _____		Replied _____		Info Copies To _____	
MILES A. H. / R & D											
Rec'd 7/22/94											
Action Copy To _____											
Replied _____											
Info Copies To _____											
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)											
<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Miles, Inc. P.O. Box 390 Shawnee Mission, KS 66201-0390</p> </div> <div style="width: 35%; border: 1px solid black; padding: 5px;"> <p>Rec'd 7/22/94</p> <p>Action Copy To _____</p> <p>Replied _____</p> <p>Info Copies To _____</p> </div> </div>											
NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.											
On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.											
A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.											
Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:											
<ol style="list-style-type: none"> 1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. 2. Make the labeling changes listed below before you release the product for shipment: <ol style="list-style-type: none"> a. Add the phrase, "EPA Registration No. 11556-115". b. Under Spray Treatments for screwworms for beef and non-lactating dairy cattle, revise the following statement: "Repeat as necessary but not more often than every 14 days." c. Under the Environmental Hazards Statement add the following statement as the second sentence in the paragraph: Do not apply directly to any body of water. 											
<input type="checkbox"/> ATTACHMENT IS APPLICABLE											
SIGNATURE OF APPROVING OFFICIAL 	DATE 7/21/94										

2

- d. Add **"Causes moderate eye irritation."** before the statement beginning "Avoid contact with skin..." in the precautionary hazards statement.
- e. Following the **IF ON SKIN** statement add,, **"Get medical attention if irritation appears."**

3. Submit five copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

4. The Confidential Statement of Formula dated March 8, 1994 will not meet the label claim for the nominal concentration for the active ingredients. The upper and lower certified limits should be calculated as follows $N \pm 5\%N$ where N is the nominal concentration of the active ingredient. Refer the PR Notice 91-2 and 40 CFR 158.175 for guidance and revised the CSF to reflect the nominal concentration of the pure active ingredient.

5. The acute oral toxicity studies (MRIDs 428498-01 and 431025-01) were acceptable and assigned Toxicity Category II Guideline. A copy of the review is enclosed for your reference.

Please let us know your intentions with respect to Co-Ral ELI product under EPA Reg. No. 11556-23. Will this product replace Co-Ral ELI product?

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

cc: Dennis McNeilly, SRRD

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (75-767)
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: ☐ REGISTRATION
☐ REREGISTRATION
(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

EPA REGISTRATION NO.

11556-115

DATE OF ISSUANCE

JUL 21 1994

TERM OF ISSUANCE

Until Reregistration

NAME OF PESTICIDE PRODUCT

Co-Ral Livestock Insecticide
Spray

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Miles, Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390

MILES A. H. / R & D

Rec'd 7/22/94

Action Copy To _____

Replied _____

Info Copies To _____

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is conditionally registered in accordance with

FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase, "EPA Registration No. 11556-115".
- b. Under Spray Treatments for screwworms for beef and non-lactating dairy cattle, revise the following statement: "Repeat as necessary but not more often than every 14 days."
- c. Under the Environmental Hazards Statement add the following statement as the second sentence in the paragraph:

Do not apply directly to any body of water.

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

for George LaRocca

DATE

7/24/94

2

- d. Add **"Causes moderate eye irritation."** before the statement beginning "Avoid contact with skin..." in the precautionary hazards statement.
- e. Following the **IF ON SKIN** statement add,, **"Get medical attention if irritation appears."**

3. Submit five copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

4. The Confidential Statement of Formula dated March 8, 1994 will not meet the label claim for the nominal concentration for the active ingredients. The upper and lower certified limits should be calculated as follows $N \pm 5\%N$ where N is the nominal concentration of the active ingredient. Refer the PR Notice 91-2 and 40 CFR 158.175 for guidance and revised the CSF to reflect the nominal concentration of the pure active ingredient.

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A stamped copy of the label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

cc: Dennis McMeilly, SRRD

(Front Panel)

Co-Ral®

(coumaphos)

FLY AND TICK SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
Inert Ingredients*:	93.85%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

Application for Pesticide
OPP No. 251090
Amendment for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115)

Enclosed for Agency acceptance are five (5) copies of draft labeling (dated 1/16/98) for Co-Ral Fly and Tick Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is identical to the labeling accepted by the Agency in an October 29, 1998 letter with only two changes.

The first change is a change in the product name from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray. This change was effected by notification (EPA Identifier No. 251089) on January 13, 1998 as per PR Notice 95-2, and approved by the Agency (letter dated January 21, 1998).

The second change is the nominal percent active ingredient has been changed from 5.8% to 6.15%, and the inert ingredients have been changed from 94.2% to 93.85%. These new percentages are the same as those listed on the current CSF (attached) which was accepted by the Agency in Notice of Pesticide Registration dated July 21, 1994.

Subsequently, Bayer Corporation received a review (dated January 5, 1998) for the Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label. The nominal percent active ingredients on the CSF and product label were technically correct since they both fall within the upper and lower limits set forth in the CSF, and have been accepted in the past by the Agency.

To resolve this, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff for guidance. Ms. DeLuise agreed that while the percent active ingredient was technically correct, it would be in clearer for everyone if the percentage stated on the product label (the nominal concentration) matched the percentage stated in column 13.b on the CSF. Thus, the enclosed draft labeling reflects this.

As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed draft labeling.

(Front Panel)

Co-Ral®

(coumaphos)

FLY AND TICK SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
Inert Ingredients*:	93.85%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

(Side Panel)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Fly and Tick Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

(Side Panel)

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Fly and Tick Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Fly and Tick Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact treated animals until their coats are dry.

PROTECTIVE CLOTHING STATEMENT

Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, shoes plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Following manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Fly and Tick Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

(Side Panel)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Fly and Tick Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.

(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
	Ticks	4	10	Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

BAYER AH R&D	
Rec'd	11/2/98
Action Copy to	
Replied	
Info. Copies to	

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

1998

Dear Mr. McNamara:

Subject: Confidential Statement of Formula- Basic Formulation
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated October 30, 1997

Your basic Confidential Statement of Formula (CSF) dated October 24, 1997 has been reviewed and is not acceptable since it is not in compliance with PR Notice 91-2. The nominal concentration (6.15%) of the active ingredient does not concur with the product label claim which is 5.8% (accepted product label October 29, 1997).

Sincerely yours,

George T. LaRocca
George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251077

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Livestock Insecticide Spray	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>	3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara	5. Date 10/30/97	

Co-Ral Livestock Insecticide Spray
EPA Reg. No. 11556-115

Explanation:

On June 11, 1997 Bayer Corporation submitted a proposal to amend the registration of Co-Ral Livestock Insecticide Spray by submitting a new Basic Confidential Statement of Formula (CSF) which reflected the nominal label value, in accordance with PR Notice 91-2.

The Agency reviewer for this CSF, Dr. Harold E. Podall met with Mr. Terry McNamara of Bayer Corp. on September 9, 1997 to discuss the way the nominal values were reported on the CSFs. Dr. Podall requested that the CSFs be revised to show that actual amount of technical compound used in the formulation, not just the nominal a.i. concentration.

Bayer is submitting this revised CSF to comply with the reviewer's request. No change in the formulation is represented by this action other than the required adjustments in the level of technical and corresponding level of inerts required as dictated by the change to the nominal value.

JAN 26 1999

Mr. F. T. McNamara
Manager, Preclinical Development
Bayer Corporation, Agricultural Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Coumaphos Product Reregistration, Repeat of Acute Toxicity Studies
EPA Registration Numbers, 11556-4, -11, -14, -20, -21, -23, -98, -115

Dear Mr. McNamara:

This is in regard to your letter dated December 30, 1998 which responds to the Agency's review of acute toxicity data for Bayer's Coumaphos products. Based on the Agency's finding acute oral, primary eye and primary dermal studies were acceptable, acute dermal was determined to be supplemental and acute inhalation, and skin sensitization studies were unacceptable. In your letter, you indicated that the studies classified as unacceptable or supplemental will be repeated and new studies will be performed and submitted within 9 months for the following:

EPA Reg. No.'s	Formulation	Percent A.I.	Studies to be Repeated
11556-4, & 11556-14	Dust	1%	81-2, Acute Dermal 81-3, Acute Inhalation 81-6, Skin Sensitization
11556-20, & 11556-21	Dust	25%	81-1, Acute Oral 81-2, Acute Dermal 81-3, Acute Inhalation 81-6, Skin Sensitization
11556-11	Technical	95.8%	81-2, Acute Dermal 81-3, Acute Inhalation 81-6, Skin Sensitization
11556-23, & 11556-115	Liquid	11.6%	81-2, Acute Dermal 81-3, Acute Inhalation
11556-98	Flowable	42%	81-2, Acute Dermal 81-3, Acute Inhalation 81-6, Skin Sensitization

You must submit the required studies by June 30, 1999. Failure to respond within this timeframe may result in regulatory action against Bayers' coumaphos product registrations. If you have any questions regarding this letter you may contact Barbara Briscoe at 703-308-8177.

Sincerely,

Linda S. Propst, Chief
Product Reregistration Branch
Special Review and
Reregistration Division

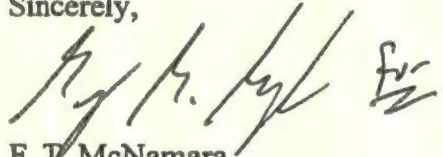
December 30, 1998

Formulation	Percent a.i.	EPA Reg. No.'s	Studies to be Repeated
Dust	1%	11556-4, 11556-14	Acute Dermal (81-2), Acute Inhalation (81-3), Skin Sensitization (81-6)
Dust	25%	11556-20, 11556-21	Acute Oral (81-1), Acute Dermal (81-2), Acute Inhalation (81-3), Skin Sensitization (81-6)
Technical	95.8%	11556-11	Acute Dermal (81-2), Acute Inhalation (81-3), Skin Sensitization (81-6)
Liquid	11.6%	11556-23, 11556-115	Acute Dermal (81-2), Acute Inhalation (81-3)
Flowable	42%	11556-98	Acute Dermal (81-2), Acute Inhalation (81-3), Skin Sensitization (81-6)

Note that the identical formulations will be grouped so that a set of studies may fulfill the requirements of more than one product. In the case of the two liquid formulations, the product to be tested (Co-Ral ELI, 11556-23) has the higher percent active ingredient (11.6% for the ELI versus 6.15% for the Fly and Tick Spray, 11556-115).

If you need additional information, please call me at (913) 268-2588.

Sincerely,



F. V. McNamara
Manager, Preclinical Development

FTM:GGG/lt

cc: George T. LaRocca (7505C)

Agriculture Division

Animal Health

Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 631-4800
Telex: 437269 Miles AHD

Via Federal Express

December 30, 1998

Linda S. Propst, Chief
Product Reregistration Branch
U.S. Environmental Protection Agency
Office of Pesticide Programs (75008W)
401 M. Street SW
Washington, DC 20460

Re: Coumaphos Toxicology Studies for Reregistration

Dear Ms. Propst:

In response to the Coumaphos RED which requested acute toxicology data for reregistration, Bayer submitted a very detailed letter (June 9, 1997) identifying the 81-1 through 81-6 toxicology studies that had been previously submitted to the Agency. Included in this submission were copies of EPA's review of each of these studies; EPA concluded all of the studies were acceptable. Nevertheless, as EPA's guidelines have changed somewhat over time, some studies, although scientifically sound, did not necessarily meet all the requirements of the new guidelines. To discuss the studies, the new guidelines and if any studies need to be repeated, Bayer requested a meeting with the Agency in a series of phone conversations with the Agency (C.P. Moran) on June 18, 20 and 24, 1997. Bayer was advised to submit all the references to current studies along with the EPA reviews of the studies; a meeting was not necessary at the time. EPA would subsequently review the package and notify Bayer if any further work was necessary.

On November 30, 1998, Bayer received a review letter from the Agency (dated November 24, 1998). The letter identified several studies as unacceptable or supplemental. In brief, Bayer will repeat all studies which have been classified as Supplemental or Unacceptable, and Bayer will provide the new studies within 9 months.

Specifically, Bayer will repeat the following toxicology studies to support the reregistration of the following products:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 24 1998

CERTIFIED MAIL

Mr. F. Terry McNamara
 Manager, Preclinical Development
 Bayer Corporation
 P.O. Box 390
 Shawnee Mission, KS 66201-0390

Subject: Coumaphos Product Reregistration - Unacceptable Studies

EPA Registration Numbers: 11556-4, -11, -14, -20, -21, -23, -98, -115

Dear Mr. McNamara

The Agency has reviewed the acute toxicity and product chemistry data for Bayers Coumaphos products and have found deficiencies in the data. The acute toxicity reviews for the above-mentioned products are enclosed. Some of these studies were determined to be unacceptable and must be redone. Other studies were determined to be supplemental and may be upgraded by the Agency to acceptable when the appropriate information is submitted.

The chemistry reviews for EPA Reg Nos. 11556-4, -14 and -98 are also enclosed for minor deficiencies. The chemistry reviews for products 11556-11, -20, -21, -23, -and -98 were determined to be acceptable and are not enclosed.

Please submit the required data or cite existing MRID's with acceptable data within 30 days of receipt of this letter. Failure to respond within this timeframe may result in a Notice of Intent to Suspend (NOIS) for Bayer's product reregistrations. If you have any questions, please contact Moana Appleyard at (703) 308-8175.

Sincerely,

Linda S. Propst, Chief
 Product Reregistration Branch
 Special Review and
 Reregistration Division



Sent to	Bayer Corp
Street and No.	
P.O. Box	3
P.O., State and ZIP Code	Shawnee Mi
Postage	
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to Whom & Date Delivered	
Return Receipt Showing Date, and Addressee's Address	
TOTAL Postage & Fees	
Postmark or Date	11/24/98
Coumaphos	
0018/1155	
23,5	

PS Form 3800, June 1991

PS Form 3800, June 1991

Enclosures

CONCURRENCES

SYMBOL	7508w	7508C					
SURNAME	Appleyard	Propst					
DATE	11/24/98	11/24/98					

via Federal Express

12/29/98

Dr. George LaRocca (7505C)
Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

cc: Linda S. Propst (7508W)
Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attachments: Application for Pesticide Amendment -
Co-Ral Animal Insecticide 1% Bulk Dust (Reg. No. 11556-14)
Application for Pesticide Amendment -
Co-Ral Fly and Tick Spray (Reg. No. 11556-115)
Application for Pesticide Amendment -
Co-Ral Animal Insecticide 1% Shaker Can (Reg No. 11556-4)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Flv and Tick Sprav	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>11/24/98</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>	3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara	5. Date <u>12/29/98</u>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 14, 1998

MEMORANDUM:

Subject: EPA Reg. No.: 11556-115/ CO-RAL® 5.8% Livestock Insecticide Spray
DP Barcode: D244400
Case No.: 18

From: Ann Hanger, Environmental Protection Specialist *AMH*
Product Reregistration Branch
Special Review and Reregistration Division (7508C) *WJP*

To: C. P. Moran, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

FORMULATION FROM EPA Reg. No.11556-115 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Coumaphos.....	6.15%
<u>Inert Ingredient(s):</u>	<u>93.85%</u>
Total	100.00%

BACKGROUND: In the 8 month response to the Coumaphos RED, the registrant has requested that the acute toxicity studies submitted for EPA Reg. No. 11556-23 be used to support the reregistration of their product, EPA Reg. No. 11556-115, a diluted form of EPA Reg. No. 11556-23. EPA Reg. No. 11556-23 is in batch 3 and EPA Reg. No. 11556-115 is not batched according to the Coumaphos RED. The MRID's are as follows: 428498-01, 431025-01, 112833, 112837, 112834, 112835, and 112836.

Data developed for EPA Reg. No. 11556-23 was accepted to support the registration of 11556-115, with the exception of the oral toxicity study. According to an EPA memorandum dated June 9, 1994, two acute oral toxicity studies (MRIDs 428498-01 and 431025-01) were accepted in order to support the registration of EPA Reg. No 11556-115. The memo confirmed that additional acute toxicity studies were not needed for the EPA Reg. No. 11556-115 because data submitted in support of the original formulation, 11556-23 supports the new registration. The two acute oral toxicity studies were conducted by Miles, Inc. using the test material CO-RAL® 6.15 % Coumaphos. The remaining studies were conducted by Bayvet's Merriam Facility, Bayvet Division, Cutter Laboratories, Inc with the exception of the inhalation study which was conducted by Mobay Chemical Corporation. The test material used in these studies was CO-RAL® 11.6 % Emulsifiable Livestock Insecticide.

Therefore, after reviewing the data evaluation reports for the submitted acute oral toxicity studies and the studies submitted for 11556-23, all studies are reviewed as acceptable to support the reregistration of EPA Reg. No. 11556-115 with the exception of the acute dermal study which is supplemental until further information is provided.

RECOMMENDATIONS:

- Four of the six acute toxicity studies (81-1, 81-4, 81-5, 81-6) are acceptable.
- The acute dermal study is supplemental and may be upgraded to acceptable upon the Agency's receipt of the size of exposure area.
- The acute inhalation study is unacceptable since particle size analysis was not determined adequately.

The acute toxicity profile for EPA Reg. No. 11556-115 is currently:

Acute Oral	II	Acceptable
Acute Dermal	III	Supplementary
Acute Inhalation		Unacceptable
Primary Eye	III	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization		Self Validated

1217567190
Regulation

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FIFRA

CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12356)

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject:

EPA Reg. #: 11556-¹¹⁵RRL; Co-Ral Livestock
Insecticide Spray

To:

George Larocca, PM # 13 Attn: Linda Arrington
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM:

David L. Ritter, Toxicologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

DLR 6-9-94

THRU::

Thomas C. Ellwanger, Jr., Ph.D., Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

Mary Ulicki
T.E.
6-7-94

Registrant:

Miles Inc.
Agriculture Division
Animal Health Products
Box 390
Shawnee Mission KN 66201

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by Wt.</u>
O,O-Diethyl O-(3-chloro-4-methyl- 2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
<u>Inert Ingredient(s):</u>	93.85%
Total	100.00%

Action Requested:

1. Review acute oral toxicity studies.
2. Comment on precautionary labeling.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Background:

Miles is submitting these two acute oral toxicity studies in rats in order to support a new formulation that has one half the AI of the original registration. The original product containing 11.6% AI was rated as a Restricted Use pesticide in the Registration Standard Second Round Review of September 1989 based on its acute oral toxicity (TOX Category I).

The proposed new formulation is a variation on #11556-23, Co-Ral Emulsifiable Livestock Insecticide. The registrant was informed in a meeting with HED on 11/29/90 that this was a new product and new acute oral toxicity data would be needed to support it. He will use the data developed for the original formulation (EPA Reg. # 11556-23) to support registration of the new formulation (EPA Reg. # 11556-RRL). See the Confidential attachment for a comparison of the two formulations.

1. Data Review:

The acute oral studies have been reviewed and the DERs are appended. MRID # 428498-01 showed an LD₅₀ of 395 mg/kg in females; TOX Category II. MRID # 431025-01 showed an LD₅₀ of 495 mg/kg in females, TOX Category II. Both studies are classified CORE Guideline.

These data results support removing the Restricted Use label provisions by moving the product from TOX category I to TOX Category II.

Additional acute data submitted in support of EPA Reg. # 11556-23 (11.6% AI) are being cited in support of the new registration. These were reviewed in the R. Zendzian memorandum of 11/17/82 which are summarized here:

Acute Toxicity Data Requirements (40 CFR §158.340).
Pesticide Assessment Guidelines, Subdivision F. Hazard Evaluation: Human and Domestic Animals. (1982; revised 1984).

Data Required	MRID #	Toxicity Category	Classification
Acute Oral (§81-1)	acc. # 248200	I	M
Acute Dermal (§81-2)	"	III	M
Acute Inhal. (§81-3)	"	III*	G
Eye Irr. (§81-4)	"	III	M
Dermal Irr. (§81-5)	"	III - or IV	M
Dermal Sens. (§81-6)	"	Non-Sens. y	M

* An examination of the study (Mobay # 81-041-16) showed that the LC₅₀ for males was 1300 mg/m³; for females it was 795 mg/m³, placing the study in TOX category III (> 0.5 - 5.0 mg/l).

Recommendation(s):

1. Removal of the "Restricted Use" classification is appropriate based on a reduction in the amount of AI in the formulation from 11.6 % AI to 6.15% AI, and new acute oral toxicity data which support a TOX Category II (LD₅₀ between 50 mg/kg and 500 mg/kg in female rats).
2. According to HED this formulation is considered to be a new registration, and new acute oral data would be required.

Additional acute toxicity studies are not needed for the new formulation because data submitted in support of the original formulation likewise support the new registration. We have summarized this data base here and offer comments on the individual studies:

Current Toxicity Data Base for 11556-23

Acute Dermal (§81-2)	III	M	LD ₅₀ > 3000 mg/kg ✓
Acute Inhal. (§81-3)	III	G	LC ₅₀ 0.795 mg/l ✓
Eye Irr. (§81-4)	III	M	Cleared by day 7. ✓
Dermal Irr. (§81-5)	III	M	" " "
Dermal Sens. (§81-6)	Non-Sens.	M	

Acute dermal study is not needed because the modest increase in percent [REDACTED] would not be expected to produce an LD₅₀ sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Acute inhalation study is not needed because the original HED TOX rating of TOX II was in error and should have been TOX III. Moreover, the LC₅₀ of 0.795 mg/l is on the low side of the TOX III range; a cut of 50% AI would not likely produce a TOX IV LC₅₀ rating. Moreover, registrant was not told this study would be needed at the HED meeting.

Eye irritation study is not required because irritation effects were reported to be most evident at day one. Thus, the modest increase in percent [REDACTED] would not be expected to produce an irritancy sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Dermal irritation study is not required because effects had vanished by day 3. Thus, the modest increase in percent [REDACTED] would not be

11556-23

81-5 IV
81-6 is a
 sensitizer

expected to produce an irritation index sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Dermal sensitisation study is not needed because the components of the new formulation are the same as those in the original formulation. Moreover, registrant was not told this study would be needed at the HED meeting.

3. Precautionary Labeling Review:

Signal Word: Acceptable

Precautionary Statements:

After the sentence, "Avoid contact ... eyes.", insert the following sentence: "Causes moderate eye irritation".

Statements of Practical Treatment:

If on Skin: Add the following: "Get medical attention.

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

Product Manager (PM): 13 EPA Reg. No.: 11556-RRL

Reviewer: David L. Ritter, Toxicologist 0425-2-94

MRID No.: 428498-01

Testing Laboratory: Miles Inc.
Toxicology
17745 South Metcalf
Stillwell, KN 66085-9104

Title Of Report: Acute Oral Toxicity Study with Coumaphos 6.15%
(CO-RAL^R) in Rats.

Date of Report: 11/2/92

Lab. No.: 92-012-PL (Miles # 103294)

Author(s): A.B. Astroff & L.L. Hagen

Species: Sprague Dawley rat Sex: 20M + 20F

Wt.: M: 174 -211 gm; F: 160 - 186 gm

Source: Sasco, Inc., St. Louis, MO.

Test Material: CO-RAL Livesock Insecticide Spray (LIS)

Dosage: See below.

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

LD₅₀ Males = 1477 mg/kg
LD₅₀ Females = 395 mg/kg

TOX Category: II; LD₅₀ between 50 mg/kg and 500 mg/kg
(females).

Core Classification: Guideline

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.
Animals were weighed initially, on day 7 and at termination.

Test Article Administration:

Test Article was administered by gavage in 0.5% aqueous methyl cellulose to groups of 5M or 5F each at doses listed here:

<u>Males mg/kg</u>	<u>Females mg/kg</u>
0	0
889	89
1870	271
2870	471

Animals were observed twice daily on weekdays and once daily on weekends for fourteen days for mortality and signs of toxicity.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Body weight gain decreased from day 0 thru 7 with recovery apparent by day 14 in the survivors.

Signs of toxicity included ataxia, tremors, torpor, fasciculations, salivation and staining.

REPORTED MORTALITY

DOSAGE MG/KG	MALES No. Dead/No. Exposed	FEMALES No. Dead/No. Exposed	COMBINED No. Dead/No. Exposed
0.0	0/5	0/5	0/10
889	0/5		0/5
1870	4/5		4/5
2870	5/5		5/5
89		0/5	0/5
(271)		0/5	0/5
471		4/5	4/5

LD₅₀ Males = 1477 mg/kg

LD₅₀ Females = 395 mg/kg

Necropsy revealed no lesions attributable to treatment.

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

Product Manager (PM): 13 EPA Reg. No.: 11556-RRL

Reviewer: David L. Ritter, Toxicologist *DLR 5-2-94*

MRID No.: 431025-01

Testing Laboratory: Miles Inc.
Toxicology
17745 South Metcalf
Stillwell, KN 66085-9104

Title Of Report: Acute Oral Toxicity Study with CO-RAL^R Livestock
Insecticide Spray in Rats.

Date of Report: 1/25/94

Lab. No.: 93-012-WT (Miles # 103294-02)

Author(s): M.A. Zorbas

Species: Sprague Dawley rat Sex: 40M + 40F

Wt.: M: 169 -228 gm; F: 145 - 180 gm

Source: Sasco, Inc., Omaha NB.

Test Material: CO-RAL Livesock Insecticide Spray

Dosage: See below.

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

LD₅₀ Males = 1011 mg/kg

LD₅₀ Females = 495 mg/kg

TOX Category: II; LD₅₀ between 50 mg/kg and 500 mg/kg
(females).

Core Classification: Guideline

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article Administration:

Animals were fasted overnight before dosing. Test Article was administered by gavage in 0.5% methyl cellulose and 0.4% Tween 80 in deionized water to groups of 5M or 5F each at doses listed here:

<u>Males mg/kg</u>	<u>Females mg/kg</u>
0	0
486	94.3
627	270
946	486
1490	571
1930	686
2800	735

Animals were observed twice daily on weekdays and once daily on weekends for fourteen days for mortality and signs of toxicity.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Body weight gain increased from day 0 through 14 in the male survivors in the 486, 627 and 946 mg/kg groups. Surviving males in the 1490 mg/kg group lost weight initially but regained some weight in the later days of the observation period. This pattern was repeated in the females.

Signs of toxicity included ataxia, torpor, fasciculations, salivation and oral, nasal and ano-genital staining. Convulsions in females was also reported.

REPORTED MORTALITY

DOSAGE MG/KG	MALES No. Dead/No. Exposed	DOSAGE N MG/KG	FEMALES No. Dead/No. Exposed
0.0	0/10	0.0	0/10
486	0/5	94.6	0/5
627	2/5	270	0/5
946	2/5	486	1/5
1490	4/5	571	5/5
1930	5/5	686	5/5
2800	5/5	735	5/5

LD₅₀ Males = 1011 mg/kg
LD₅₀ Females = 495 mg/kg

Necropsy revealed no lesions attributable to treatment.

ACUTE TOX ONE-LINER

1. PC CODE: 036501; Coumaphos
2. CURRENT DATE: 4/22/94
3. TEST MATERIAL: Co-Ral Livestock Insecticide Spray
4. EPA Reg. #: 11556-RRL

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Acute oral/Rat/Miles /92-012-PL/11/2/92	428498-01	LD ₅₀ M = 1477 mg/kg LD ₅₀ F = 395 mg/kg	II	G
Acute oral/Rat/Miles /92-012-PL/11/2/92	431025-01	LD ₅₀ M = 1011 mg/kg LD ₅₀ F = 495 mg/kg	II	G

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary

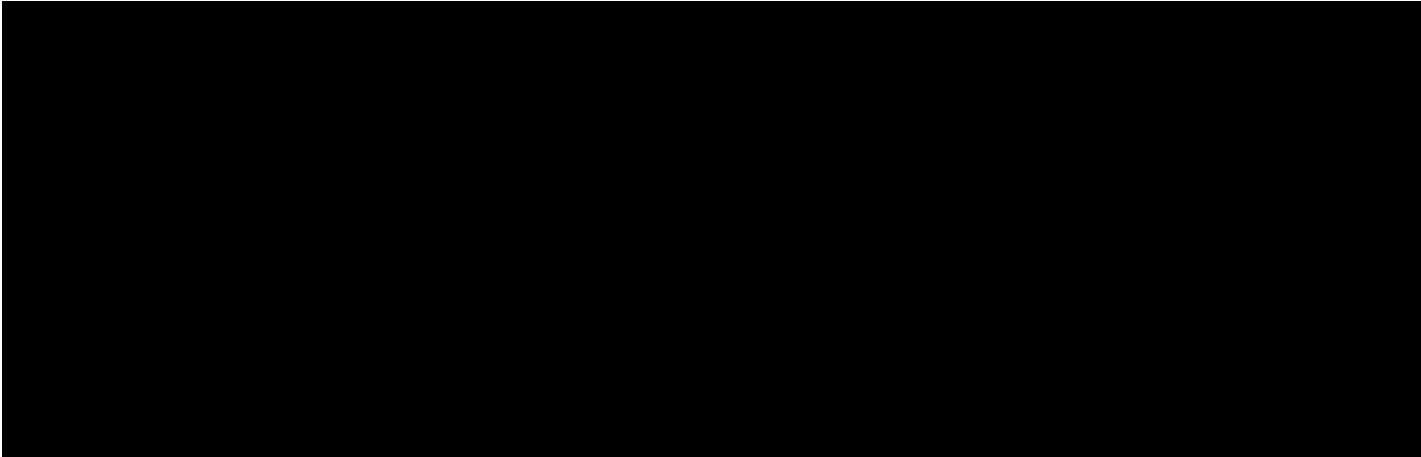
062 S-2-94

CONFIDENTIAL ATTACHMENT

EPA Reg. # 11556-RRL; Co-Ral Livestock Insecticide Spray
Discussion of Inert Ingredients.

The registrant is basing support for the subject formulation on toxicity data obtained from the previous formula. Specifically, he is diluting the AI (coumaphos) at 11.6 % down to 6.15% and making up the difference with [REDACTED] as follows:

<u>Component</u>	<u>EPA Reg.# 11556-23</u>	<u>EPA Reg.# 11556-RRL</u>
Coumaphos Technical	11.9%	6.15%



Application for Pesticide
OPP No. 251091
Confidential Statement of Formula for Co-Ral Fly and Tick Spray
(EPA Reg. No. 11556-115); Agency Letter dated January 5, 1998

Enclosed for Agency review and acceptance is a Confidential Statement of Formula (CSF) for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115).

In explanation, on October 30, 1997, Bayer submitted an application for a revised Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The Agency responded in a January 5, 1998 letter which stated the CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label.

The percent active ingredient on the label was 5.8% (the nominal concentration). Although 5.8% is between the upper and lower certified limits of 5.5% and 6.8%, respectively on the CSF, the midpoint of the certified limits is 6.15% and this value is in column 13.b of the CSF.

To obtain guidance on how to resolve this matter, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff. Ms. DeLuise agreed that while the percent active ingredients listed were technically correct, it would be clearer for everyone if the percentage stated on the product label matched the midpoint of the upper and lower certified limits stated on the CSF.

Accordingly, Bayer has submitted an application for label amendment to revise the nominal concentration on the label from 5.8% to 6.15% (a copy of this application is enclosed). Please note, in the interim Bayer has changed the name of the product from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray by a January 12, 1998 notification to the Agency and accepted by the Agency (letter dated January 21, 1998).

The enclosed CSF is identical to that which Bayer submitted earlier on October 30, 1997 and the Agency previously reviewed in the Agency's January 5, 1998 letter, with only one change. The product name on the enclosed CSF is Co-Ral Fly and Tick Spray to reflect the name change of the product (again, effected by a January 12, 1998 notification).

When the Agency accepts the revised labeling, the Agency should also accept the enclosed CSF. As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed CSF.

Application for Pesticide
OPP No. 251090
Amendment for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115)

Enclosed for Agency acceptance are five (5) copies of draft labeling (dated 1/16/98) for Co-Ral Fly and Tick Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is identical to the labeling accepted by the Agency in an October 29, 1998 letter with only two changes.

The first change is a change in the product name from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray. This change was effected by notification (EPA Identifier No. 251089) on January 13, 1998 as per PR Notice 95-2, and approved by the Agency (letter dated January 21, 1998).

The second change is the nominal percent active ingredient has been changed from 5.8% to 6.15%, and the inert ingredients have been changed from 94.2% to 93.85%. These new percentages are the same as those listed on the current CSF (attached) which was accepted by the Agency in Notice of Pesticide Registration dated July 21, 1994.

Subsequently, Bayer Corporation received a review (dated January 5, 1998) for the Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label. The nominal percent active ingredients on the CSF and product label were technically correct since they both fall within the upper and lower limits set forth in the CSF, and have been accepted in the past by the Agency.

To resolve this, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff for guidance. Ms. DeLuise agreed that while the percent active ingredient was technically correct, it would be in clearer for everyone if the percentage stated on the product label (the nominal concentration) matched the percentage stated in column 13.b on the CSF. Thus, the enclosed draft labeling reflects this.

As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed draft labeling.

Reason to Issue: Response to Agency letter dated
January 5, 1998

Date: 1/16/98
Supersedes: 10/3/97
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

FLY AND TICK SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
Inert Ingredients*:	93.85%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

(Side Panel)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Fly and Tick Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

(Side Panel)

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Fly and Tick Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Fly and Tick Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact treated animals until their coats are dry.

PROTECTIVE CLOTHING STATEMENT

Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, shoes plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Following manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Fly and Tick Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

(Side Panel)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Fly and Tick Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.

(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting. Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Attachment 5
PRODUCT CHEMISTRY REVIEW748
8/17/93

TO: PM 13 FROM: Reviewer: INDIRA CHAIROLA Date: 08/16/93
 EPA REG. NO.: 11556-RRL PRODUCT NAME: CO-RAI, LiveStock Insecticide Spr

FOOD USE () INERTS CLEARED: C (), D (), E () NON FOOD USE ()
 21 CFR PARTS 170-199: () TOXIC INERTS LIST 1 (), 2 ()

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry data for your product. ☐ If submitted earlier, provide MRID Number(s). ☐ Your product is not sufficiently similar to the product you referenced.

2. In reference to the Confidential Statement of Formula (CSF), please provide the following:

- ☐ a) pH of product or pH at a specified water dilution.
☐ b) Density of product.
☐ c) Flash point of product.
☐ d) Flash point of product with propellant as per item #6(q) or item #5(c).
☐ e) Flame extension of product including flashbacks if noted.
☒ f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.

- ☐ g) The upper and lower certified limits of the individually added inerts.

- ☐ h) Your label claim for Active ingredient is 5.8%. Hence 13b. or

$$1. \text{ by wt. } (6.15\%) \times \text{purity of Technical } (90.0\%) = 5.54\% \text{ This}$$

☐ i) is below the declared label claim of 5.8%. Moreover your
☐ j) Certified limits should be bracketed around this amount (Nominal).
 the limits should be \pm or $-$ 3% of Nominal % when calculated in pure active form.

3. ☒ Based on the current CSF dated 06/29/93, your product will ~~not meet~~ ^{Not meet} the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.

The CSF will be accepted after the stated corrections are made.

Note: According to our records purity of source product #11556-11 is 90.0%. All the calculations are based on this concentration.

-2-

Attachment 5

PRODUCT CHEMISTRY REVIEW (cont'd)

4. ☒ Provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

1. [REDACTED]

2.

3.

4.

5.

The supplier may contact EPA directly referencing the File Symbol or EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are non-food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

- ☐ a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with ☐ PR Notice 84-1 for non-aerosol containers for houses and institutional uses or ☐ PR Notice 83-3 for all other uses.
- ☐ b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h)(2)(iii).
- ☐ c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellants).
- ☐ d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.
- ☐ e) Add a footnote to the inert ingredients indicating: Contains aromatic petroleum distillates, xylene or xylene-range aromatic solvent.
- ☐ f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

Do not use this product in or on electrical equipment
due to the possibility of shock hazard.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

BAYER AH R&D

Rec'd	2/23/98
Action Copy to	
Replied	
Info. Copies to	

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Confidential Statement of Formula- Basic Formulation
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated January 26, 1998

Your basic Confidential Statement of Formula (CSF)
dated January 28, 1998 has been reviewed and is acceptable.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

via Federal Express 1/29/98

Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

cc: Mr. George T. LaRocca
Ms. Linda DeLuise

bc: R. G. Arther
C. L. Basel
D. D. Cox
L. Fought
G. G. Gagliano
R. Henry
T. R. Lenz
F. T. McNamara
A. Pishny
J. Rueter
Reg. Book

Attachments: • Application for Pesticide Amendment (OPP #251090)
• Labeling Co-Ral® (coumaphos) Fly and Tick Spray
(EPA Reg. No. 11556-115) - 5 copies
• Confidential Statement of Formula



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251090

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>		3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara		5. Date 1/26/98	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251091

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>		3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara		5. Date 1/26/98	

149

via Federal Express 1/29/98

Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

cc: Mr. George T. LaRocca
Ms. Linda DeLuise

bc: R. G. Arther
C. L. Basel
D. D. Cox
L. Fought
G. G. Gagliano
R. Henry
T. R. Lenz
F. T. McNamara
A. Pishny
J. Rueter
Reg. Book

Attachments: • Application for Pesticide Amendment (OPP #251091)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251091

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>		3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara		5. Date 1/26/98	

Application for Pesticide
OPP No. 251091
Confidential Statement of Formula for Co-Ral Fly and Tick Spray
(EPA Reg. No. 11556-115); Agency Letter dated January 5, 1998

Enclosed for Agency review and acceptance is a Confidential Statement of Formula (CSF) for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115).

In explanation, on October 30, 1997, Bayer submitted an application for a revised Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The Agency responded in a January 5, 1998 letter which stated the CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label.

The percent active ingredient on the label was 5.8% (the nominal concentration). Although 5.8% is between the upper and lower certified limits of 5.5% and 6.8%, respectively on the CSF, the midpoint of the certified limits is 6.15% and this value is in column 13.b of the CSF.

To obtain guidance on how to resolve this matter, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff. Ms. DeLuise agreed that while the percent active ingredients listed were technically correct, it would be clearer for everyone if the percentage stated on the product label matched the midpoint of the upper and lower certified limits stated on the CSF.

Accordingly, Bayer has submitted an application for label amendment to revise the nominal concentration on the label from 5.8% to 6.15% (a copy of this application is enclosed). Please note, in the interim Bayer has changed the name of the product from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray by a January 12, 1998 notification to the Agency and accepted by the Agency (letter dated January 21, 1998).

The enclosed CSF is identical to that which Bayer submitted earlier on October 30, 1997 and the Agency previously reviewed in the Agency's January 5, 1998 letter, with only one change. The product name on the enclosed CSF is Co-Ral Fly and Tick Spray to reflect the name change of the product (again, effected by a January 12, 1998 notification).

When the Agency accepts the revised labeling, the Agency should also accept the enclosed CSF. As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed CSF.

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> <input checked="" type="checkbox"/> X <input type="checkbox"/>	Registration Amendment Other	OPP Identifier Number <div style="font-size: 24pt; font-weight: bold;">251090</div>

Application for Pesticide - Section I

1. Company/Product Number <div style="text-align: center; font-weight: bold;">11556-115</div>	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# <div style="text-align: center;">13</div>	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <div style="text-align: center; font-weight: bold;">(Stamped)</div>
2. Signature 	3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara	5. Date <div style="font-size: 24pt; font-family: cursive;">1/26/98</div>	

Application for Pesticide
OPP No. 251090
Amendment for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115)

Enclosed for Agency acceptance are five (5) copies of draft labeling (dated 1/16/98) for Co-Ral Fly and Tick Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is identical to the labeling accepted by the Agency in an October 29, 1998 letter with only two changes.

The first change is a change in the product name from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray. This change was effected by notification (EPA Identifier No. 251089) on January 13, 1998 as per PR Notice 95-2, and approved by the Agency (letter dated January 21, 1998).

The second change is the nominal percent active ingredient has been changed from 5.8% to 6.15%, and the inert ingredients have been changed from 94.2% to 93.85%. These new percentages are the same as those listed on the current CSF (attached) which was accepted by the Agency in Notice of Pesticide Registration dated July 21, 1994.

Subsequently, Bayer Corporation received a review (dated January 5, 1998) for the Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label. The nominal percent active ingredients on the CSF and product label were technically correct since they both fall within the upper and lower limits set forth in the CSF, and have been accepted in the past by the Agency.

To resolve this, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff for guidance. Ms. DeLuise agreed that while the percent active ingredient was technically correct, it would be in clearer for everyone if the percentage stated on the product label (the nominal concentration) matched the percentage stated in column 13.b on the CSF. Thus, the enclosed draft labeling reflects this.

As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed draft labeling.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

253402

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral (coumaphos) Livestock Insecticide Spray	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt.		No. per container	If "Yes" Package wgt.	No. per container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. T. McNamara	Title Biochemistry & Pesticide Registrations Manager	Telephone No. (Include Area Code) (913) 268-2588
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
3. Signature 		
3. Title Biochemistry & Pesticide Registrations Manager		
4. Typed Name F. T. McNamara		5. Date October 3, 1997

ATTACHMENT FOR OPP #253402
APPLICATION FOR PESTICIDE AMENDMENT

Enclosed for Agency acceptance are 5 copies of draft labeling, dated 10/3/97, for Co-Ral (coumaphos) Livestock Insecticide Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is based on the label which the Agency accepted on 7/21/94 with the changes detailed below. The proposed label changes enclosed with this submission are based on EPA comments in a CBRS 11/15/94 memorandum and the 8/96 Reregistration Eligibility Decision (RED).

Specifically, the following are the changes from the 7/21/94 accepted labeling:

- 1) The enclosed draft labeling reflects our corporate name change from Miles Inc. to Bayer Corp.
- 2) Previous labeling contained the following statement under the Protective Clothing Statement section:

“USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders and dip vat tank workers must wear a chemical resistant apron and face shield or goggles and a NIOSH/MSHA approved respiratory protection device.”

With the enclosed draft labeling, we are proposing to revise this statement using the statement required by the RED which includes the glove statement established for coumaphos in Supplement Three of PR Notice 93-7. The proposed statement reads as follows:

“Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, shoes plus socks.”

“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”

"Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Follow manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

- 3) On the enclosed draft labeling, we have deleted all recommendations for control of screwworms on cattle and horses by spray applications.
- 4) Previous labeling contained the following statement for cattle under the Remarks section for the Horn Flies and Lice use pattern:

"Repeat as necessary."

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

"Treat no more than six times per year. Do not make applications less than 10 days apart."

- 5) Previous labeling contained the following statement for cattle under the Remarks section for the Ticks use pattern:

"Repeat as necessary."

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

"Treat no more than six times per year. Do not make applications less than 10 days apart."

- 6) Previous labeling contained the following statement for lactating dairy cattle under the Remarks section for the Lice use pattern:

"Repeat as necessary."

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

"Treat no more than six times per year. Do not make applications less than 10 days apart."

- 7) Previous labeling contained the following statement for horses under the Remarks section for the Horn Flies and Lice use pattern:

“Repeat as necessary.”

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

“Treat no more than six times per year. Do not make applications less than 10 days apart.”

- 8) Previous labeling contained the following statement for horses under the Remarks section for the Ticks use pattern:

“Repeat as necessary.”

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

“Treat no more than six times per year. Do not make applications less than 10 days apart.”

- 9) Previous labeling contained the following statement for swine under the Remarks section for the Lice use pattern:

“Repeat as necessary.”

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

“Treat no more than six times per year. Do not make applications less than 10 days apart.”

- 10) The following section and statement has been added to the label under the Directions for Use in accordance with the RED:

“Entry Restriction: Do not contact treated animals until their coats are dry.”

- 11) The following statements have been added to the label under the Use Restrictions section in accordance with the RED:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

"Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc."

- 12) The following statements have been added to the label under the Environmental Hazards section in accordance with the RED:

"Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate."

- 13) The following section and statements have been added to the label in accordance with the RED with the exception that the term "feed bunk" replaces "drinking cup" as specified on the RED because drinking cups are not used for cattle. In addition, the words "or drink" were added for clarity.

"Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment."

Please note, the proposed revisions in the use directions do not add any uses (animals or pests); do not increase any use rates; and are more restrictive than the currently registered use directions which permit "Repeat as necessary" applications.

As all, except one, of the proposed modifications in the enclosed labeling were Agency requested, and as none of the proposed modifications require data review, we anticipate ready Agency acceptance of the proposed labeling.

Included with this application are two completed and signed "Certification with Respect to Citation of Data" forms indicating the General Offer to Pay although all data cited in EPA's September, 1989 "Registration Standard (Second Round Review) for the Registration of Pesticide Products Containing Coumaphos as the Active Ingredient," are Bayer (formerly Miles, Mobay and Bayvet) data or public literature data.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

LIVESTOCK INSECTICIDE SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	5.8%
Inert Ingredients*:	94.2%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

(Side Panel)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Livestock Insecticide Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

(Side Panel)

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Livestock Insecticide Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Livestock Insecticide Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact treated animals until their coats are dry.

PROTECTIVE CLOTHING STATEMENT

Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber ≥ 14 mils, shoes plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Following manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Livestock Insecticide Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

(Side Panel)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Livestock Insecticide Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at ½ maximum label rate, etc.

(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY
CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 7 of 8

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¼ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
	Ticks	4	10	Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Continued)

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 8 of 8

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 02-28-

Certification with Respect to Citation of Data

Applicant's Name and Address

Bayer Corporation
Agriculture Division, Animal Health
PO Box 390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number 11556-115

Product Name Co-Ral (coumaphos) Livestock
Insecticide Spray

Date of Application October 3, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)
2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.
 - I am the original submitter*; or
 - I have obtained the written permission of the original submitter for _____, which is
(insert name of chemical)
(for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*
3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;
 - a.
 - I am the original data submitter*; or
 - I have obtained the written permission of the original data submitter for _____, which is
(insert name of chemical)
(for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*; or
 - b. I have notified in writing the companies _____ for _____ that
(insert names of companies) (insert name of chemical)
have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
listed on the Pesticide Data Submitters List for all active ingredients contained in my product
(cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer
Statement below.)
Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
that have submitted the studies which I have cited (Selective method*).
4. I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature

Name and Title

Date

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

Name and Title

F. T. McNamara, Biochemistry &
Pesticide Registrations Manager

Date October 3, 1997



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FIFRA
CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12356)

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. #: 11556-RRL; Co-Ral Livestock
Insecticide Spray

To: George Larocca, PM # 13 Attn: Linda Arrington
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: David L. Ritter, Toxicologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W) *DOR 6-9-94*

THRU:: Thomas C. Ellwanger, Jr., Ph.D., Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (7505W) *Mary Waller
T.E.
6/9/94*

Registrant: Miles Inc.
Agriculture Division
Animal Health Products
Box 390
Shawnee Mission KN 66201

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by Wt.</u>
O,O-Diethyl O-(3-chloro-4-methyl- 2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
<u>Inert Ingredient(s):</u>	93.85%
Total	100.00%

Action Requested:

1. Review acute oral toxicity studies.
2. Comment on precautionary labeling.



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Background:

Miles is submitting these two acute oral toxicity studies in rats in order to support a new formulation that has one half the AI of the original registration. The original product containing 11.6% AI was rated as a Restricted Use pesticide in the Registration Standard Second Round Review of September 1989 based on its acute oral toxicity (TOX Category I).

The proposed new formulation is a variation on #11556-23, Co-Ral Emulsifiable Livestock Insecticide. The registrant was informed in a meeting with HED on 11/29/90 that this was a new product and new acute oral toxicity data would be needed to support it. He will use the data developed for the original formulation (EPA Reg. # 11556-23) to support registration of the new formulation (EPA Reg. # 11556-RRL). See the Confidential attachment for a comparison of the two formulations.

1. Data Review:

The acute oral studies have been reviewed and the DERs are appended. MRID # 428498-01 showed an LD₅₀ of 395 mg/kg in females; TOX Category II. MRID # 431025-01 showed an LD₅₀ of 495 mg/kg in females, TOX Category II. Both studies are classified CORE Guideline.

These data results support removing the Restricted Use label provisions by moving the product from TOX category I to TOX Category II.

Additional acute data submitted in support of EPA Reg. # 11556-23 (11.6% AI) are being cited in support of the new registration. These were reviewed in the R. Zendzian memorandum of 11/17/82 which are summarized here:

Acute Toxicity Data Requirements (40 CFR §158.340).
Pesticide Assessment Guidelines, Subdivision F. Hazard Evaluation: Human and Domestic Animals. (1982; revised 1984).

Data Required	MRID #	Toxicity Category	Classification
Acute Oral (§81-1)	acc. # 248200	I	M
Acute Dermal (§81-2)	"	III	M
Acute Inhal. (§81-3)	"	III*	G
Eye Irr. (§81-4)	"	III	M
Dermal Irr. (§81-5)	"	III	M
Dermal Sens. (§81-6)	"	Non-Sens.	M

* An examination of the study (Mobay # 81-041-16) showed that the LC₅₀ for males was 1300 mg/m³; for females it was 795 mg/m³, placing the study in TOX category III (> 0.5 - 5.0 mg/l).

Recommendation(s):

1. Removal of the "Restricted Use" classification is appropriate based on a reduction in the amount of AI in the formulation from 11.6 % AI to 6.15% AI, and new acute oral toxicity data which support a TOX Category II (LD₅₀ between 50 mg/kg and 500 mg/kg in female rats).
2. According to HED this formulation is considered to be a new registration, and new acute oral data would be required.

Additional acute toxicity studies are not needed for the new formulation because data submitted in support of the original formulation likewise support the new registration. We have summarized this data base here and offer comments on the individual studies:

Current Toxicity Data Base for 11556-23

Acute Dermal (§81-2)	III	M	LD ₅₀ > 3000 mg/kg
Acute Inhal. (§81-3)	III	G	LC ₅₀ 0.795 mg/l
Eye Irr. (§81-4)	III	M	Cleared by day 7.
Dermal Irr. (§81-5)	III	M	" " "
Dermal Sens. (§81-6)	Non-Sens.	M	

Acute dermal study is not needed because the modest increase in percent [REDACTED] would not be expected to produce an LD₅₀ sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Acute inhalation study is not needed because the original HED TOX rating of TOX II was in error and should have been TOX III. Moreover, the LC₅₀ of 0.795 mg/l is on the low side of the TOX III range; a cut of 50% AI would not likely produce a TOX IV LC₅₀ rating. Moreover, registrant was not told this study would be needed at the HED meeting.

Eye irritation study is not required because irritation effects were reported to be most evident at day one. Thus, the modest increase in percent [REDACTED] would not be expected to produce an irritancy sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Dermal irritation study is not required because effects had vanished by day 3. Thus, the modest increase in percent [REDACTED] would not be

expected to produce an irritation index sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Dermal sensitization study is not needed because the components of the new formulation are the same as those in the original formulation. Moreover, registrant was not told this study would be needed at the HED meeting.

3. Precautionary Labeling Review:

Signal Word: Acceptable

Precautionary Statements:

After the sentence, "Avoid contact ... eyes.", insert the following sentence: "Causes moderate eye irritation".

Statements of Practical Treatment:

If on Skin: Add the following: "Get medical attention."

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

Product Manager (PM): 13 EPA Reg. No.: 11556-RRL

Reviewer: David L. Ritter, Toxicologist 0425-2-94

MRID No.: 428498-01

Testing Laboratory: Miles Inc.
Toxicology
17745 South Metcalf
Stillwell, KN 66085-9104

Title Of Report: Acute Oral Toxicity Study with Coumaphos 6.15%
(CO-RAL^R) in Rats.

Date of Report: 11/2/92

Lab. No.: 92-012-PL (Miles # 103294)

Author(s): A.B. Astroff & L.L. Hagen

Species: Sprague Dawley rat Sex: 20M + 20F

Wt.: M: 174 -211 gm; F: 160 - 186 gm

Source: Sasco, Inc., St. Louis, MO.

Test Material: CO-RAL Livesock Insecticide Spray (LIS)

Dosage: See below.

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

LD₅₀ Males = 1477 mg/kg
LD₅₀ Females = 395 mg/kg

TOX Category: II; LD₅₀ between 50 mg/kg and 500 mg/kg
(females).

Core Classification: Guideline

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article Administration:

Test Article was administered by gavage in 0.5% aqueous methyl cellulose to groups of 5M or 5F each at doses listed here:

<u>Males mg/kg</u>	<u>Females mg/kg</u>
0	0
889	89
1870	271
2870	471

Animals were observed twice daily on weekdays and once daily on weekends for fourteen days for mortality and signs of toxicity.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Body weight gain decreased from day 0 thru 7 with recovery apparent by day 14 in the survivors.

Signs of toxicity included ataxia, tremors, torpor, fasciculations, salivation and staining.

REPORTED MORTALITY

DOSAGE MG/KG	MALES No. Dead/No. Exposed	FEMALES No. Dead/No. Exposed	COMBINED No. Dead/No. Exposed
0.0	0/5	0/5	0/10
889	0/5		0/5
1870	4/5		4/5
2870	5/5		5/5
89		0/5	0/5
271		0/5	0/5
471		4/5	4/5

LD₅₀ Males = 1477 mg/kg

LD₅₀ Females = 395 mg/kg

Necropsy revealed no lesions attributable to treatment.

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

Product Manager (PM): 13 EPA Reg. No.: 11556-RRL

Reviewer: David L. Ritter, Toxicologist DLR 5-2-94

MRID No.: 431025-01

Testing Laboratory: Miles Inc.
Toxicology
17745 South Metcalf
Stillwell, KN 66085-9104

Title Of Report: Acute Oral Toxicity Study with CO-RAL^R Livestock
Insecticide Spray in Rats.

Date of Report: 1/25/94

Lab. No.: 93-012-WT (Miles # 103294-02)

Author(s): M.A. Zorbas

Species: Sprague Dawley rat Sex: 40M + 40F

Wt.: M: 169 -228 gm; F: 145 - 180 gm

Source: Sasco, Inc., Omaha NB.

Test Material: CO-RAL Livesock Insecticide Spray

Dosage: See below.

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

LD₅₀ Males = 1011 mg/kg
LD₅₀ Females = 495 mg/kg

TOX Category: II; LD₅₀ between 50 mg/kg and 500 mg/kg
(females).

Core Classification: Guideline

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article Administration:

Animals were fasted overnight before dosing. Test Article was administered by gavage in 0.5% methyl cellulose and 0.4% Tween 80 in deionized water to groups of 5M or 5F each at doses listed here:

<u>Males mg/kg</u>	<u>Females mg/kg</u>
0	0
486	94.3
627	270
946	486
1490	571
1930	686
2800	735

Animals were observed twice daily on weekdays and once daily on weekends for fourteen days for mortality and signs of toxicity.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Body weight gain increased from day 0 through 14 in the male survivors in the 486, 627 and 946 mg/kg groups. Surviving males in the 1490 mg/kg group lost weight initially but regained some weight in the later days of the observation period. This pattern was repeated in the females.

Signs of toxicity included ataxia, torpor, fasciculations, salivation and oral, nasal and ano-genital staining. Convulsions in females was also reported.

REPORTED MORTALITY

DOSAGE MG/KG	MALES No. Dead/No. Exposed	DOSAGE N MG/KG	FEMALES No. Dead/No. Exposed
0.0	0/10	0.0	0/10
486	0/5	94.6	0/5
627	2/5	270	0/5
946	2/5	486	1/5
1490	4/5	571	5/5
1930	5/5	686	5/5
2800	5/5	735	5/5

LD₅₀ Males = 1011 mg/kg

LD₅₀ Females = 495 mg/kg

Necropsy revealed no lesions attributable to treatment.

ACUTE TOX ONE-LINER

1. PC CODE: 036501; Coumaphos
2. CURRENT DATE: 4/22/94
3. TEST MATERIAL: Co-Ral Livestock Insecticide Spray
4. EPA Reg. #: 11556-RRL

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Acute oral/Rat/Miles /92-012-PL/11/2/92	428498-01	LD ₅₀ M = 1477 mg/kg LD ₅₀ F = 395 mg/kg	II	G
Acute oral/Rat/Miles /92-012-PL/11/2/92	431025-01	LD ₅₀ M = 1011 mg/kg LD ₅₀ F = 495 mg/kg	II	G

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary

042 5-2-94

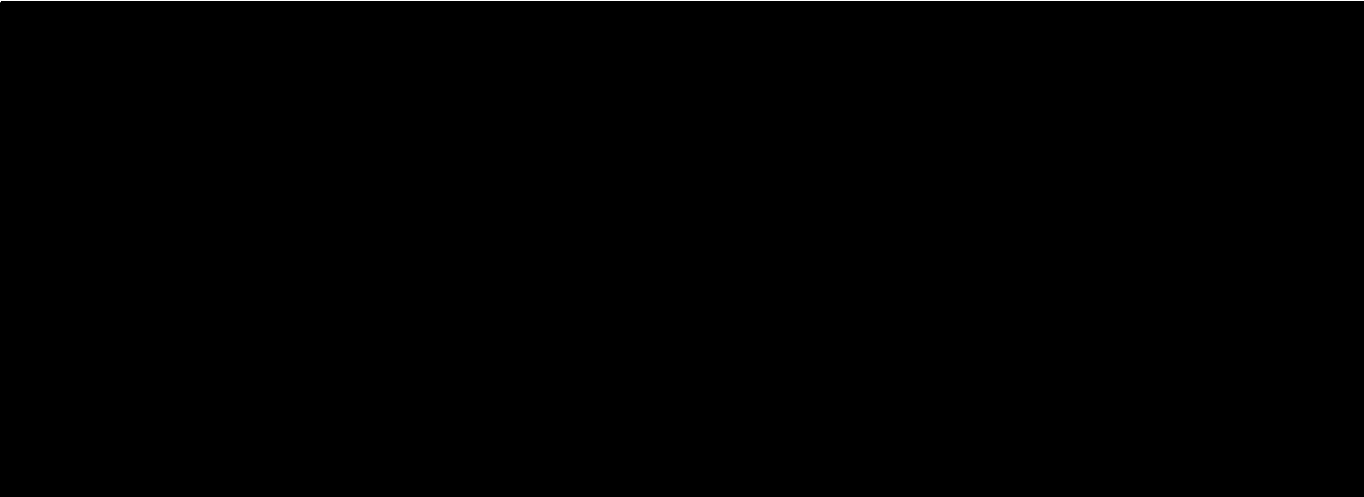
CONFIDENTIAL ATTACHMENT

EPA Reg. # 11556-RRL; Co-Ral Livestock Insecticide Spray
Discussion of Inert Ingredients.

The registrant is basing support for the subject formulation on toxicity data obtained from the previous formula. Specifically, he is diluting the AI (coumaphos) at 11.6 % down to 6.15% and making up the difference with [REDACTED]

[REDACTED] as follows:

<u>Component</u>	<u>EPA Reg.# 11556-23</u>	<u>EPA Reg.# 11556-RRL</u>
Coumaphos Technical	11.9%	6.15%



Inert ingredient information may be entitled to confidential treatment

(Side Panel)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Fly and Tick Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

(Side Panel)

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Fly and Tick Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Fly and Tick Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact treated animals until their coats are dry.

PROTECTIVE CLOTHING STATEMENT

Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, shoes plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Following manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Fly and Tick Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

(Side Panel)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Fly and Tick Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.

(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting. Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION
INSECTICIDE-RODENTICIDE BRANCH

Fax Number (703) 305-6596

FACSIMILE REQUEST / COVER SHEET

(Please type or print in BLACK INK only)

SEND FAX TO:

NAME: Terry McNamara

OFF: Miles Inc

FAX PHONE NUMBER: 913-268-2541

OFFICE PHONE NUMBER: 913-268-2588

FROM:

NAME: Lucinda Arington

DIVISION/BRANCH: RDHED

OFFICE PHONE NUMBER: 703 305 5420

OFFICE ROOM NUMBER: 202

MAIL CODE: 7505C

DATE: 10/21/93

TIME: 3

NUMBER OF PAGES (WITH COVER SHEET):

Special Message --- describe below:

Copy of the Chemistry reviews to follow
the ~~final~~ ~~review~~ ~~of~~ ~~the~~ ~~study~~ ~~is~~ ~~still~~
under review.

Lucinda

MRID 42874501

MILES A.H./R&D	
Rec'd	<u>10/21/93</u>
Action Copy To	_____
Replied	_____
Info Copies To	_____
_____	_____
_____	_____

Attachment 5
PRODUCT CHEMISTRY REVIEW

TO: PM 13 FROM: Reviewer: INDIRA CHAIROLA Date: 08/16/93
 EPA REG. NO.: 11556-RRL PRODUCT NAME: CO-RAI, live stock Insecticide Spr

FOOD USE () INERTS CLEARED: C (), D (), E () NON FOOD USE ()
 21 CFR PARTS 170-199: () TOXIC INERTS LIST 1 (), 2 ()

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry data for your product. ☐ If submitted earlier, provide MRID number(s). ☐ Your product is not sufficiently similar to the product you referenced.

2. In reference to the Confidential Statement of Formula (CSF), please provide the following:

- ☐ a) pH of product or pH at a specified water dilution.
☐ b) Density of product.
☐ c) Flash point of product.
☐ d) Flash point of product with propellant as per item #6(a) or item #5(c).
☐ e) Flame extension of product including flashbacks if noted.
☒ f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.

- ☐ g) The upper and lower certified limits of the individually added inerts.

- ☐ h) Your label claim for Active ingredient is 5.8%. Hence 13b. or % by wt. (6.15%) x purity of Technical (90.0%) = 5.54%. This is below the declared label claim of 5.8%. Moreover your
☐ i) Certified limits should be bracketed around this amount (Nominal).
☐ j) The limits should be + or - 3% of Nominal % when calculated in pure active form.

3. ☒ Based on the current CSF dated 06/29/93, your product will ~~not meet~~ ^{Not meet} the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.

The CSF will be accepted after the stated corrections are made.

Note: According to our records purity of source product #11556-11 is 90.0%. All the calculations are based on this concentration.

-2-

Attachment 5

PRODUCT CHEMISTRY REVIEW (cont'd)

4. ☒ Provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

1. [REDACTED]

2.

3.

4.

5.

The supplier may contact EPA directly referencing the File Symbol or EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are non-food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

- ☐ a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with ☐ PR Notice 84-1 for non-aerosol containers for houses and institutional uses or ☐ PR Notice 83-3 for all other uses.
- ☐ b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10 (h) (2) (iii).
- ☐ c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellants).
- ☐ d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.
- ☐ e) Add a footnote to the inert ingredients indicating: Contains aromatic petroleum distillates, xylene or xylene-range aromatic solvent.
- ☐ f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

Do not use this product in or on electrical equipment
due to the possibility of shock hazard.

Inert ingredient information may be entitled to confidential treatment

via Federal Express 1/29/98

Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

cc: Mr. George T. LaRocca
Ms. Linda DeLuise

bc: R. G. Arther
C. L. Basel
D. D. Cox
L. Fought
G. G. Gagliano
R. Henry
T. R. Lenz
F. T. McNamara
A. Pishny
J. Rueter
Reg. Book

Attachments: • Application for Pesticide Amendment (OPP #251091)



United States
Environmental Protection Agency
Washington, DC 20460

☐
☒ X
☐

Registration
Amendment
Other

OPP Identifier Number

251091

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. T. McNamara		Title Manager, Preclinical Development	
		Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature F. T. McNamara		3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara		5. Date 1/26/98	

102

Application for Pesticide
OPP No. 251091
Confidential Statement of Formula for Co-Ral Fly and Tick Spray
(EPA Reg. No. 11556-115); Agency Letter dated January 5, 1998

Enclosed for Agency review and acceptance is a Confidential Statement of Formula (CSF) for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115).

In explanation, on October 30, 1997, Bayer submitted an application for a revised Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The Agency responded in a January 5, 1998 letter which stated the CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label.

The percent active ingredient on the label was 5.8% (the nominal concentration). Although 5.8% is between the upper and lower certified limits of 5.5% and 6.8%, respectively on the CSF, the midpoint of the certified limits is 6.15% and this value is in column 13.b of the CSF.

To obtain guidance on how to resolve this matter, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff. Ms. DeLuise agreed that while the percent active ingredients listed were technically correct, it would be clearer for everyone if the percentage stated on the product label matched the midpoint of the upper and lower certified limits stated on the CSF.

Accordingly, Bayer has submitted an application for label amendment to revise the nominal concentration on the label from 5.8% to 6.15% (a copy of this application is enclosed). Please note, in the interim Bayer has changed the name of the product from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray by a January 12, 1998 notification to the Agency and accepted by the Agency (letter dated January 21, 1998).

The enclosed CSF is identical to that which Bayer submitted earlier on October 30, 1997 and the Agency previously reviewed in the Agency's January 5, 1998 letter, with only one change. The product name on the enclosed CSF is Co-Ral Fly and Tick Spray to reflect the name change of the product (again, effected by a January 12, 1998 notification).

When the Agency accepts the revised labeling, the Agency should also accept the enclosed CSF. As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed CSF.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251090

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>	3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara	5. Date 1/26/98	

Application for Pesticide
OPP No. 251090
Amendment for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115)

Enclosed for Agency acceptance are five (5) copies of draft labeling (dated 1/16/98) for Co-Ral Fly and Tick Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is identical to the labeling accepted by the Agency in an October 29, 1998 letter with only two changes.

The first change is a change in the product name from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray. This change was effected by notification (EPA Identifier No. 251089) on January 13, 1998 as per PR Notice 95-2, and approved by the Agency (letter dated January 21, 1998).

The second change is the nominal percent active ingredient has been changed from 5.8% to 6.15%, and the inert ingredients have been changed from 94.2% to 93.85%. These new percentages are the same as those listed on the current CSF (attached) which was accepted by the Agency in Notice of Pesticide Registration dated July 21, 1994.

Subsequently, Bayer Corporation received a review (dated January 5, 1998) for the Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label. The nominal percent active ingredients on the CSF and product label were technically correct since they both fall within the upper and lower limits set forth in the CSF, and have been accepted in the past by the Agency.

To resolve this, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff for guidance. Ms. DeLuise agreed that while the percent active ingredient was technically correct, it would be in clearer for everyone if the percentage stated on the product label (the nominal concentration) matched the percentage stated in column 13.b on the CSF. Thus, the enclosed draft labeling reflects this.

As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed draft labeling.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 29 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Amendment- label changes
Co- Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated October 3, 1997

BAYER AH R&D	
Rec'd	11/3/97
Action Copy to	
Replied	
Info. Copies to	

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a copy of a stamped label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

LIVESTOCK INSECTICIDE SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	5.8%
Inert Ingredients*:	94.2%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

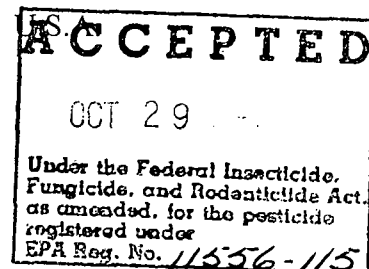
KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201



Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 2 of 8

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 3 of 8

(Side Panel)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Livestock Insecticide Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

(Side Panel)

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Livestock Insecticide Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Livestock Insecticide Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact treated animals until their coats are dry.

PROTECTIVE CLOTHING STATEMENT

Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, shoes plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Following manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Livestock Insecticide Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 5 of 8

(Side Panel)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Livestock Insecticide Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 6 of 8

(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY
CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting. Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	

(Continued)

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 8 of 8

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

BAYER AH R&D

Rec'd	11/2/98
Action Copy to	
Replied	
Info. Copies to	

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

1998

Dear Mr. McNamara:

Subject: Confidential Statement of Formula- Basic Formulation
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated October 30, 1997

Your basic Confidential Statement of Formula (CSF) dated October 24, 1997 has been reviewed and is not acceptable since it is not in compliance with PR Notice 91-2. The nominal concentration (6.15%) of the active ingredient does not concur with the product label claim which is 5.8% (accepted product label October 29, 1997).

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251077

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Livestock Insecticide Spray	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. T. McNamara		Title Manager, Preclinical Development	
		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature F. T. McNamara		3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara		5. Date 10/30/97	

Co-Ral Livestock Insecticide Spray
EPA Reg. No. 11556-115

Explanation:

On June 11, 1997 Bayer Corporation submitted a proposal to amend the registration of Co-Ral Livestock Insecticide Spray by submitting a new Basic Confidential Statement of Formula (CSF) which reflected the nominal label value, in accordance with PR Notice 91-2.

The Agency reviewer for this CSF, Dr. Harold E. Podall met with Mr. Terry McNamara of Bayer Corp. on September 9, 1997 to discuss the way the nominal values were reported on the CSFs. Dr. Podall requested that the CSFs be revised to show that actual amount of technical compound used in the formulation, not just the nominal a.i. concentration.

Bayer is submitting this revised CSF to comply with the reviewer's request. No change in the formulation is represented by this action other than the required adjustments in the level of technical and corresponding level of inerts required as dictated by the change to the nominal value.

D. Labeling Changes Summary Table

Table 8 contains labeling changes previously identified in the 1996 Coumaphos RED and additional changes established in this RED Addendum for coumaphos. Labeling changes from both REDs should be incorporated in their entirety into labels for coumaphos-containing products, in order for currently registered uses of coumaphos to be eligible for reregistration. The PPE that would be established on the basis of acute toxicity category of the end-use product must be compared to the active-ingredient-based personal protective equipment specified in Table 8. The more protective PPE should be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Table 8: Summary of Labeling Changes for Coumaphos		
Description	Amended Labeling Language	Placement on Label
Manufacturing-Use Products		
Formulation Restriction	"Only for formulation into an insecticide for the following use(s): beef cattle, dairy cattle, horses, swine and swine bedding."	Directions for Use
	"This product may not be used to formulate products for use in mechanical dusters."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	<p>"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."</p> <p>"This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."</p>	Directions for Use

Table 8: Summary of Labeling Changes for Coumaphos

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements
End-Use Products Intended for Occupational Use (Non-WPS)		
Restricted Use Pesticide Statements for the 42% Flowable and 11.6% EC Products (EPA Reg. Nos. 11556-98 and 11556-23)	"RESTRICTED USE PESTICIDE: Due to Acute Oral Hazard- For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification"	Top of Front Panel
Use Restriction Statement for the 42% Flowable Product (EPA Reg. No. 11556-98)	"Use restricted to employees of the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) who are enrolled in the USDA-APHIS cholinesterase monitoring program."	Front panel, immediately following the Restricted Use Pesticide statement

Table 8: Summary of Labeling Changes for Coumaphos

Description	Amended Labeling Language	Placement on Label
<p>Handler PPE Requirements for the 42% Flowable Product (EPA Reg. No. 11556-98)</p>	<p>“Some materials that are chemical-resistant to this products are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, and others exposed to the concentrate (such as during a spill or equipment breakdown) and all other handlers participating in dip-vat applications must wear:</p> <ul style="list-style-type: none"> *long-sleeve shirt and long pants, *chemical-resistant gloves, *chemical-resistant footwear plus socks, *chemical-resistant apron, and *face shield or goggles. <p>All other handlers, including spray applicators, must wear:</p> <ul style="list-style-type: none"> *long-sleeve shirt and long pants, *chemical-resistant gloves, and *chemical-resistant footwear plus socks.” 	<p>Precautionary Statement Directly below the Hazards to Humans and Domestic Animals</p>

Table 8: Summary of Labeling Changes for Coumaphos

Description	Amended Labeling Language	Placement on Label
<p>Handler PPE Requirements for the 11.6% and 6.15% Emulsifiable Concentrate Products (EPA Reg. Nos. 11556-23 and 11556-115)</p>	<p>“Some materials that are chemical-resistant to this products are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, and others exposed to the concentrate (such as during a spill or equipment breakdown) must wear:</p> <ul style="list-style-type: none"> *long-sleeve shirt and long pants, *chemical-resistant gloves, *chemical-resistant footwear plus socks, *chemical-resistant apron, and *face shield or goggles. <p>Applicators and all other handlers exposed to the dilute must wear:</p> <ul style="list-style-type: none"> *long-sleeve shirt and long pants, *chemical-resistant gloves, and *chemical-resistant footwear plus socks.” 	<p>Precautionary Statement Directly below the Hazards to Humans and Domestic Animals</p>

Table 8: Summary of Labeling Changes for Coumaphos

Description	Amended Labeling Language	Placement on Label
Handler PPE Requirements for all Bulk Dust Products	<p>"Some materials that are chemical-resistant to this products are" (<i>registrant inserts correct chemical-resistant material</i>). "If you want more options, follow the instructions for category" [<i>registrant inserts A, B, C, D, E, F, G, or H</i>] "on an EPA chemical-resistance category selection chart."</p> <p>"Loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> *long sleeve shirt and long pants, *chemical-resistant gloves, *shoes plus socks, *chemical-resistant apron, *a NIOSH-approved dust/mist respirator, with MSHA/NIOSH approval number prefix TC21C or a NIOSH-approved respirator with any N[*] R, P, or HE filter." 	Precautionary Statements Directly below the Hazards to Humans and Domestic Animals
Handler PPE Requirements for all Ready-to-Use Dust Products	<p>"Some materials that are chemical-resistant to this products are" (<i>registrant inserts correct chemical-resistant material</i>). "If you want more options, follow the instructions for category" [<i>registrant inserts A, B, C, D, E, F, G, or H</i>] "on an EPA chemical-resistance category selection chart."</p> <p>"Applicators and other handlers must wear:</p> <ul style="list-style-type: none"> *long sleeve shirt and long pants, *chemical-resistant gloves, *shoes plus socks, *chemical-resistant apron, *a NIOSH-approved dust/mist respirator, with MSHA/NIOSH approval number prefix TC21C or a NIOSH-approved respirator with any N[*] R, P, or HE filter." 	Precautionary Statements Directly below the Hazards to Humans and Domestic Animals

Table 8: Summary of Labeling Changes for Coumaphos

Description	Amended Labeling Language	Placement on Label
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from the other laundry."	Precautionary Statements Directly below the PPE
Engineering Controls or Improved Packaging for all Liquid Products	EPA requires that all liquid concentrate formulations be contained in "no-glug" containers, water-soluble gel packs, or other equivalent methods approved by the Agency.	Not for placement on label
User Safety Recommendations	<p>"User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."</p>	Precautionary Statements Directly below the User Safety Requirements (must be placed in a box)
Environmental Hazards	<p>"This pesticide is toxic to mammals, birds, fish and aquatic invertebrates.</p> <p>Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms.</p> <p>Do not contaminate water when disposing of equipment washwater or rinsate."</p>	Precautionary Statements under Environmental Hazards

Table 8: Summary of Labeling Changes for Coumaphos

Description	Amended Labeling Language	Placement on Label
Disposal Restriction Statement for the 42% Flowable Product (EPA Reg. No. 11556-98)	"Cattle Dip Solution Disposal: The Agency requires that spent dip-vat solution be bioremediated, and recommends the bioremediation method developed by the USDA. The treated solution must be transferred to shallow, concrete-lined evaporation ponds for further degradation. The evaporation ponds must be constructed to prevent overflow or flooding during wet seasons and must be lined with reinforced concrete. Dried sludge generated in the evaporation ponds must not be applied to agricultural land and should be disposed according to solid waste disposal regulations established by your Local and/or State Environmental Control Agency. Questions concerning the disposal of the spent solution should be directed to the waste representative at the nearest EPA Regional Office."	Directions for Use under Storage and Disposal
Re-entry Restriction for Liquid Products	"Entry Restrictions: Do not contact or allow others to contact treated animals until their coats are dry."	Directions for Use under General Precautions and Restrictions
Re-Entry Restriction for Dust Products	"Entry Restrictions: Do not enter treated areas or allow contact with treated animals until dusts have settled."	Directions for Use under General Precautions and Restrictions

Placement on Label

Directions for Use under Application Restrictions

Directions for Use under Application Restrictions

Directions for Use under Application Restrictions

Directions for Use under Application Restrictions

Table 8: Summary of Labeling Changes for Coumaphos		
Description	Amended Labeling Language	Placement on Label
Application Restriction for all Liquid Products	"Do not spray in a confined, non-ventilated area."	Directions for Use under Application Restrictions
Application Restriction for all Liquid and Dust Products	"Do not treat areas such as drinking cups, mangers, or troughs where livestock feed. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment."	Directions for Use under Application Restrictions
Application Restriction for all Products	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may in the area during application."	Directions for Use under Application Restrictions
Application Restriction for Products Applied by Hand Held Sprayer	"Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at ½ maximum label rate, etc."	Directions for Use under Application Restrictions
Application Restriction for all Dust Products	"Individuals must limit the number of animals they can treat per day with shaker can to no more than 25 and the area of swine bedding they can treat per day to 1,000 sq. ft."	Directions for Use under Application Restrictions
Application Restriction for all Dust Products	"The use of mechanical dusters is prohibited."	Directions for Use under Application Restrictions
Application Restrictions	Move the Application Restrictions section to the beginning of the Directions for Use section	Beginning of Directions for Use
Use Deletion for all Dust Products	The use of mechanical dusters are no longer supported by the technical registrant and will be deleted from all dust products.	Not for placement on label

* If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

Instructions in the Labeling Required section appearing in quotations represent the exact language that must appear on the label.

Instructions in the Labeling Required section not in quotes represents actions that the registrant must take to amend their labels or product registrations.

MAR - 8 1998
MAR - 8 1998

Mr. F.T. McNamara
Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Confidential Statement of Formula- Basic Formulation
Co-Ral Fly and Tick Spray
EPA Registration Number 11556-115
Your submission dated December 29, 1998

Your alternate Confidential Statement of Formula (CSF)
dated December 28, 1998 has been reviewed and is acceptable.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

DATE OUT: 03/MAR/1999

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]**
BARCODE No.: 252396 EPA RECEIVED DATE: 30/DEC/1998 REG./File Symbol No.: 11556-115
PRODUCT NAME: Co-Ral Fly and Tick Spray, 6.15% Coumaphos Technical MRID Nos.: None
COMPANY NAME: Bayer Corporation Action Code: 345

FROM: Sami Malak, Chemist /S/
Technical Review Branch/RD (7505C)

TO: 03 Arnold Layne/Linda DeLuise
Insecticide Branch/RD (7505C)

INTRODUCTION:

The applicant, Bayer Corp, responded to EPA Letter of 24/NOV/1998 and submitted a revised CSF, a basic formulation dated 18/DEC/1998, for this end-use product, Co-Ral Fly and Tick Spray, Reg. No. 11556-115. The product contains 6.15% Coumaphos Technical.

FINDINGS:

1. The subject product is formulated form a technical source containing 96% coumaphos technical, Reg. No. 11556-11.
2. Revisions to product's CSF, a basic formulation dated 18/DEC/1998, were in compliance with EPA's letter of 24/NOV/1998. The CSF reflects a nominal concentration of 6.15% consistent with the label claim.
3. The submitted product's CSF a basic formulations dated 18/DEC/1998 was filled out correctly and completely in compliance with the regulations. The nominal concentration of the active ingredient agrees with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations.

CONCLUSIONS:

The applicant complied with EPA's letter of 24/NOV/1998 and made the necessary revisions to product's CSF, a basic formulation dated 18/DEC/1998. It is acceptable & should supersede corresponding previous basic formulations.

Co-submitter LD

via Federal Express

12/29/98

Dr. George LaRocca (7505C)
Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

cc: Linda S. Propst (7508W)
Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attachments: Application for Pesticide Amendment -
Co-Ral Animal Insecticide 1% Bulk Dust (Reg. No. 11556-14)
Application for Pesticide Amendment -
Co-Ral Fly and Tick Spray (Reg. No. 11556-115)
Application for Pesticide Amendment -
Co-Ral Animal Insecticide 1% Shaker Can (Reg No. 11556-4)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Flv and Tick Sprav	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>11/24/98</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Plastic
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>	3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara	5. Date <u>12/29/98</u>	

5537801

FEB 19 1998

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Confidential Statement of Formula- Basic Formulation
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated January 26, 1998

Your basic Confidential Statement of Formula (CSF)
dated January 28, 1998 has been reviewed and is acceptable.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

FEB 19 1998

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Amendment- label changes
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated January 26, 1998

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a copy of a stamped label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Reason to Issue: Response to Agency letter dated
January 5, 1998

Date: 1/16/98
Supersedes: 10/3/97
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

FLY AND TICK SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
Inert Ingredients*:	93.85%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated

FEB 19 1998

J:\users\linda\labelspr\GGG0008a.lab

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

11556-115 223

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

(Side Panel)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Fly and Tick Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

(Side Panel)

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Fly and Tick Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Fly and Tick Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact treated animals until their coats are dry.

PROTECTIVE CLOTHING STATEMENT

Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, shoes plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Following manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Fly and Tick Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

(Side Panel)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Fly and Tick Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at ½ maximum label rate, etc.

(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

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(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon). Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting. Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

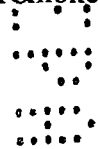
STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



Application for Pesticide
OPP No. 251090
Amendment for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115)

Enclosed for Agency acceptance are five (5) copies of draft labeling (dated 1/16/98) for Co-Ral Fly and Tick Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is identical to the labeling accepted by the Agency in an October 29, 1998 letter with only two changes.

The first change is a change in the product name from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray. This change was effected by notification (EPA Identifier No. 251089) on January 13, 1998 as per PR Notice 95-2, and approved by the Agency (letter dated January 21, 1998).

The second change is the nominal percent active ingredient has been changed from 5.8% to 6.15%, and the inert ingredients have been changed from 94.2% to 93.85%. These new percentages are the same as those listed on the current CSF (attached) which was accepted by the Agency in Notice of Pesticide Registration dated July 21, 1994.

Subsequently, Bayer Corporation received a review (dated January 5, 1998) for the Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label. The nominal percent active ingredients on the CSF and product label were technically correct since they both fall within the upper and lower limits set forth in the CSF, and have been accepted in the past by the Agency.

To resolve this, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff for guidance. Ms. DeLuise agreed that while the percent active ingredient was technically correct, it would be in clearer for everyone if the percentage stated on the product label (the nominal concentration) matched the percentage stated in column 13.b on the CSF. Thus, the enclosed draft labeling reflects this.

As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed draft labeling.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251090

Application for Pesticide - Section I.

1. Company/Product Number 11556-115	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Fly and Tick Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attached

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name F. T. McNamara		Title Manager, Preclinical Development		Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>		3. Title Manager, Preclinical Development			
4. Typed Name F. T. McNamara		5. Date 1/26/98			



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

264634

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

- VOID -

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/>		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name		Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature		3. Title	
4. Typed Name		5. Date	

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20480

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

264634

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

- VOID -

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/>		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name		Title		Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamped)
2. Signature		3. Title		
4. Typed Name		5. Date		

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Application for Pesticide
OPP No. 251091
Confidential Statement of Formula for Co-Ral Fly and Tick Spray
(EPA Reg. No. 11556-115); Agency Letter dated January 5, 1998

Enclosed for Agency review and acceptance is a Confidential Statement of Formula (CSF) for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115).

In explanation, on October 30, 1997, Bayer submitted an application for a revised Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The Agency responded in a January 5, 1998 letter which stated the CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label.

The percent active ingredient on the label was 5.8% (the nominal concentration). Although 5.8% is between the upper and lower certified limits of 5.5% and 6.8%, respectively on the CSF, the midpoint of the certified limits is 6.15% and this value is in column 13.b of the CSF.

To obtain guidance on how to resolve this matter, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff. Ms. DeLuise agreed that while the percent active ingredients listed were technically correct, it would be clearer for everyone if the percentage stated on the product label matched the midpoint of the upper and lower certified limits stated on the CSF.

Accordingly, Bayer has submitted an application for label amendment to revise the nominal concentration on the label from 5.8% to 6.15% (a copy of this application is enclosed). Please note, in the interim Bayer has changed the name of the product from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray by a January 12, 1998 notification to the Agency and accepted by the Agency (letter dated January 21, 1998).

The enclosed CSF is identical to that which Bayer submitted earlier on October 30, 1997 and the Agency previously reviewed in the Agency's January 5, 1998 letter, with only one change. The product name on the enclosed CSF is Co-Ral Fly and Tick Spray to reflect the name change of the product (again, effected by a January 12, 1998 notification).

When the Agency accepts the revised labeling, the Agency should also accept the enclosed CSF. As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed CSF.

FEB 19 1998

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Confidential Statement of Formula- Basic Formulation
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated January 26, 1998

Your basic Confidential Statement of Formula (CSF)
dated January 28, 1998 has been reviewed and is acceptable.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

DATE OUT: 17/FEB/1998

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]**
BARCODE No.: 242773 EPA RECEIVED DATE: 30/JAN/1998 REG./File Symbol No.: 11556-115
PRODUCT NAME: Co-Ral Fly and Tick Spray, 6.15% Coumaphos Technical MRID Nos.: None
COMPANY NAME: Bayer Corporation Action Code: 346

FROM: Sami Malak, Chemist /S/
Technical Review Branch/Registration Division (7505C)

TO: 03 Susan Lewis/Linda DeLuise
Insecticide Branch/Registration Division (7505C)

INTRODUCTION:

With this re-submission, the applicant, Bayer Corp, responded to EPA Letter of 05/JAN/1998 and submitted a revised label EPA received 30/JAN/1998 and a revised CSF, a basic formulation dated 28/JAN/1998, for this end-use product, Co-Ral Fly and Tick Spray. The product contains 6.15% Coumaphos Technical.

FINDINGS:

The applicants complied with EPA letter of 05/JAN/1998 and made the following revisions to product's label and CSF:

1. Product's label, EPA received 30/JAN/1998, reflects: (a) a change in product's name from Co-Ral Livestock Insecticide to Co-Ral Fly and Tick Spray. The name change was approved by the Agency in a letter dated 21/JAN/1998; and (b) Change in the nominal concentration from 5.8% to 6.15% for consistency with the claim on product's CSF.
2. Product's CSF, a basic formulation dated 28/JAN/1998, reflects a nominal concentration of 6.15% for consistency with label claim. The upper and lower certified limits are consistent with the nominal concentration's concept as per the regulations of PR Notice 91-2.

CONCLUSIONS:

The applicant complied with EPA's letter of 05/JAN/1998 and made the requested revisions to product's label, EPA received 30/JAN/1998, and CSF, a basic formulation dated 28/JAN/1998. The label and CSF are acceptable.

NOTE TO CRM:

The applicant should be advised to revise product's label to included a statement regarding the "Storage and Disposal" of this product.

Application for Pesticide

OPP No. 251090

Amendment for Co-Ral Fly and Tick Spray (EPA Reg. No. 11556-115)

Enclosed for Agency acceptance are five (5) copies of draft labeling (dated 1/16/98) for Co-Ral Fly and Tick Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is identical to the labeling accepted by the Agency in an October 29, 1998 letter with only two changes.

The first change is a change in the product name from Co-Ral Livestock Insecticide Spray to Co-Ral Fly and Tick Spray. This change was effected by notification (EPA Identifier No. 251089) on January 13, 1998 as per PR Notice 95-2, and approved by the Agency (letter dated January 21, 1998).

The second change is the nominal percent active ingredient has been changed from 5.8% to 6.15%, and the inert ingredients have been changed from 94.2% to 93.85%. These new percentages are the same as those listed on the current CSF (attached) which was accepted by the Agency in Notice of Pesticide Registration dated July 21, 1994.

Subsequently, Bayer Corporation received a review (dated January 5, 1998) for the Confidential Statement of Formula (CSF) for Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115). The CSF was deemed unacceptable since the percent active ingredient on the CSF did not agree with the percent active on product label. The nominal percent active ingredients on the CSF and product label were technically correct since they both fall within the upper and lower limits set forth in the CSF, and have been accepted in the past by the Agency.

To resolve this, on January 15, 1998, Greg Gagliano, Bayer scientific and regulatory specialist, contacted Linda DeLuise of your staff for guidance. Ms. DeLuise agreed that while the percent active ingredient was technically correct, it would be in clearer for everyone if the percentage stated on the product label (the nominal concentration) matched the percentage stated in column 13.b on the CSF. Thus, the enclosed draft labeling reflects this.

As the proposed action does not require any new data review, we anticipate the Agency will expeditiously accept the enclosed draft labeling.

1/26/98

JAN 21 1998

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

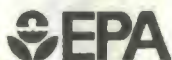
Dear Mr. McNamara:

Subject: Amendment- product name change
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated January 13, 1998

The Agency acknowledges receipt of your amendment to change the above product name to Co-Ral Fly and Tick Spray. The new name of this product is Co-Ral Fly and Tick Spray.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

251089

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager <i>T. Levine</i>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Livestock Insecticide Spray	PM# 04	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See attached

Product Name Change

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
Certification must be submitted If "Yes" Unit Packaging wgt. No. per container If "Yes" Package wgt. No. per container				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name F. T. McNamara		Title Manager, Preclinical Development		Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					On Date Application Received (Stamped)
2. Signature <i>F. T. McNamara</i>		3. Title Manager, Preclinical Development			
4. Typed Name F. T. McNamara		5. Date 1/13/98			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 88-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Place in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, reregistration, etc.

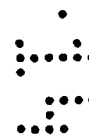
- 1-5. Self-explanatory.
6. EPA Use Only.

APPLICATION FOR PESTICIDE

OPP No. 251089

Notification of Product Name Change per PR Notice 95-2.

Bayer Corporation, Animal Health is changing the name of its product Co-Ral Livestock Insecticide Spray (EPA Reg. No. 11556-115) to Co-Ral Fly and Tick Spray.



JAN -5 1998

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

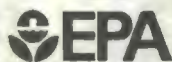
Dear Mr. McNamara:

Subject: Confidential Statement of Formula- Basic Formulation
Co-Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated October 30, 1997

Your basic Confidential Statement of Formula (CSF) dated October 24, 1997 has been reviewed and is not acceptable since it is not in compliance with PR Notice 91-2. The nominal concentration (6.15%) of the active ingredient does not concur with the product label claim which is 5.8% (accepted product label October 29, 1997).

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

251077

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Livestock Insecticide Spray	PM# 03	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. T. McNamara	Title Manager, Preclinical Development	Telephone No. (Include Area Code) _____
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped) _____ _____ _____
2. Signature F. T. McNamara	3. Title Manager, Preclinical Development	
4. Typed Name F. T. McNamara	5. Date 10/30/97	

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3. **Proposed Classification** - Specify the proposed classification of this product.
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5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Comments) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "no top" reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

DATE: December 29, 1997

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D240861 REG./File Symbol No.: 11556-115
PRODUCT NAME: CO-RAL Livestock Insecticide Spray
COMPANY: Bayer Corporation

FROM: Shyam B. Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

S. Mathur
12-29-97

TO: Susan Lewis, PM 03
Insecticide Branch/RD(7505C)

INTRODUCTION

The Agency requested (September 9, 1997) the registrant to revise the Basic Confidential Statement of Formula of this product in compliance with PR Notice 91-2, which will reflect the nominal label value.

SUMMARY OF FINDINGS

The Bayer Corporation submitted the revised basic formulation CSF dated 10-28-97. The basic formulation CSF (dated 10-28-97) is not acceptable since it is not in compliance with PR Notice 91-2. The nominal concentration (6.15%) of the active ingredient does not concur with the product label claim which is 5.8% (accepted Product label dated October 29, 1997).

CONCLUSION

The basic formulation CSF (dated October 28, 1997) is not acceptable. The registrant must submit a revised CSF which must be in accordance with PR Notice 91-2, according to which the nominal concentration of the active ingredient must concur with the product label claim of the active ingredient.

~~645/5532132~~
175

OCT 29 1997

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 300
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Amendment- label changes
Co- Ral Livestock Insecticide Spray
EPA Registration Number 11556-115
Your submission dated October 3, 1997

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a copy of a stamped label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

LIVESTOCK INSECTICIDE SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	Percent by Weight
Active Ingredient:	
0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	5.8%
Inert Ingredients*:	94.2%
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

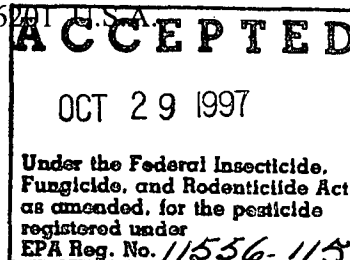
KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Bayer Corporation
Agriculture Division
Animal Health
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.



Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 2 of 8

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 3 of 8

(Side Panel)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Bayer Corporation

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Livestock Insecticide Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

(Side Panel)

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Livestock Insecticide Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Livestock Insecticide Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact treated animals until their coats are dry.

PROTECTIVE CLOTHING STATEMENT

Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber ≥ 14 mils, shoes plus socks.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Following manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Livestock Insecticide Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 5 of 8

(Side Panel)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Livestock Insecticide Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

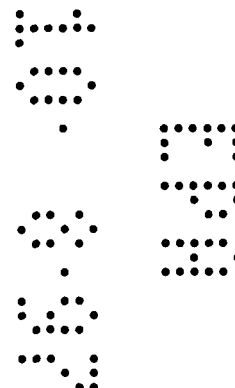
Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at ½ maximum label rate, etc.



(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY
CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 7 of 8

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
	Ticks	4	10	Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.

(Continued)

Reason to Issue: To propose changes in accordance
with the RED

Date: 10/3/97
Supersedes: 7/7/94
Page 8 of 8

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DP BARCODE: D240194

CASE: 034529
SUBMISSION: S532137

DATA PACKAGE RECORD
BEAN SHEET

DATE: 10/23/97
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 655 FORM DATA & LBL - REREG
RANKING : 5 POINTS ()
CHEMICALS: 036501 Coumaphos

5.8000%

ID#: 011556-00115 CO-RAL LIVESTOCK INSECTICIDE SPRAY
COMPANY: 011556 BAYER CORP
PRODUCT MANAGER: 03 SUSAN LEWIS 703-305-7448 ROOM: CM2 217
PM TEAM REVIEWER: LINDA DELUISE 703-305-5420 ROOM: CM2
RECEIVED DATE: 10/08/97 DUE OUT DATE: 02/05/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 240194 EXPEDITE: N DATE SENT: 10/23/97 DATE RET.: / /
CHEMICAL: 036501 Coumaphos
DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: Y
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 01/21/98
DIV : RD / / / / NEGOT DATE: / /
BRAN: IB / / / / PROJ DATE: / /
SECT: PM03 / / / /
REVR : / / / /
CONTR: / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

on team

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------

JACKETS (Fileroom Document Tracking System)
Requested Jackets Report (New Requests)

10/23/97
08:17:16
OYOUNG

Requested by : DELUISE, L

Barcode : 021307

Agency : EPA Office : OPPTS Program : OPP
Division : RD Branch : IB Section :

Requested on 10/23/97 at 08:06

Jacket Barcode	Regulatory Case File #	Vol/Total	Location	Status
000520130	011556-00014	1 / 1	41 / A / 04 / 3	A:12/71
000025300	011556-00098	1 / 1	42 / B / 01 / 3	A:10/81
000345290	011556-00115	1 / 1	45 / A / 03 / 2	A:07/94
000270780	011556-00021	2 / 2	15 / B / 06 / 3	A:12/71
000105020	011556-00004	1 / 1	41 / A / 02 / 2	A:03/72
000025350	011556-00023	1 / 1	40 / A / 06 / 2	A:12/71
000520150	011556-00011	1 / 1	25 / A / 07 / 3	A:12/71
000025360	011556-00020	1 / 1	42 / B / 05 / 2	A:12/71

Total # of jackets requested : 8

Completed: 9 Date: 10/23 Time: 8:35

DELUISE, L



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

253402

Application for Pesticide - Section I

1. Company/Product Number 11556-115	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral (coumaphos) Livestock Insecticide Spray	PM# 03-S. Lewis	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation Agriculture Division, Animal Health PO Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name F. T. McNamara		Title Biochemistry & Pesticide Registrations Manager		Telephone No. (Include Area Code) (913) 268-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature F. T. McNamara		3. Title Biochemistry & Pesticide Registrations Manager			
4. Typed Name F. T. McNamara		5. Date October 3, 1997			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 02-28-95

Certification with Respect to Citation of Data

Applicant's Name and Address
Bayer Corporation
Agriculture Division, Animal Health
PO Box 1390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number 11556-115

Product Name Co-Ral (coumaphos) Livestock
Insecticide Spray

Date of Application October 3, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

☐ I am the original submitter*; or

☐ I have obtained the written permission of the original submitter for _____, which is
(insert name of chemical)
_____ (for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

a. ☐ I am the original data submitter*; or

☐ I have obtained the written permission of the original data submitter for _____, which is
(insert name of chemical)
_____ (for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*; or

b. ☐ I have notified in writing the companies _____ for _____ that
(insert names of companies) (insert name of chemical)

have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
listed on the Pesticide Data Submitters List for all active ingredients contained in my product
(cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer
Statement below.)

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
that have submitted the studies which I have cited (Selective method*).

4. ☐ I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature

Name and Title

Date

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

Name and Title

F. T. McNamara, Biochemistry &
Pesticide Registrations Manager

Date October 3, 1997



United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 02-28-95

Certification with Respect to Citation of Data

Applicant's Name and Address

Bayer Corporation
Agriculture Division, Animal Health
PO Box 390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number 11556-115

Product Name Co-Ral (coumaphos) Livestock
Insecticide Spray

Date of Application October 3, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

I am the original submitter*; or

I have obtained the written permission of the original submitter for _____, which is
(insert name of chemical)
(for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

a. I am the original data submitter*; or

I have obtained the written permission of the original data submitter for _____, which is
(insert name of chemical)
(for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*; or

b. I have notified in writing the companies _____ for _____ that
(insert names of companies) (insert name of chemical)

have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
listed on the Pesticide Data Submitters List for all active ingredients contained in my product
(cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer
Statement below.)

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
that have submitted the studies which I have cited (Selective method*).

4. I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature

Name and Title

Date

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

Name and Title F. T. McNamara, Biochemistry &
Pesticide Registrations Manager

Date October 3, 1997

Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

- Attachments:
- Application for Pesticide Amendment (OPP #244553) - Co-Ral (coumaphos)
Flowable Insecticide
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data
 - Application for Pesticide Amendment (OPP #244552) - Co-Ral (coumaphos)
Animal Insecticide 1% Shaker Can
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data
 - Application for Pesticide Amendment (OPP #253401) - Co-Ral (coumaphos)
Emulsifiable Livestock Insecticide
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data
 - Application for Pesticide Amendment (OPP #253399) - Co-Ral (coumaphos)
Animal Insecticide 25% Wettable Powder
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data
 - Application for Pesticide Amendment (OPP #253400) - Co-Ral (coumaphos)
25% Dust Base
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data
 - Application for Pesticide Registration (OPP #253403) - Coumaphos Technical
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data
 - Application for Pesticide Registration (OPP #244554) - Co-Ral (coumaphos)
Animal Insecticide 1% Bulk Dust
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data
 - Application for Pesticide Registration (OPP #253402) - Co-Ral (coumaphos)
Livestock Insecticide Spray
 - 5 copies Draft Labeling
 - 2 copies Certification with Respect to Citation of Data

ATTACHMENT FOR OPP #253402
APPLICATION FOR PESTICIDE AMENDMENT

Enclosed for Agency acceptance are 5 copies of draft labeling, dated 10/3/97, for Co-Ral (coumaphos) Livestock Insecticide Spray, EPA Reg. No. 11556-115. The enclosed draft labeling is based on the label which the Agency accepted on 7/21/94 with the changes detailed below. The proposed label changes enclosed with this submission are based on EPA comments in a CBRS 11/15/94 memorandum and the 8/96 Reregistration Eligibility Decision (RED).

Specifically, the following are the changes from the 7/21/94 accepted labeling:

- 1) The enclosed draft labeling reflects our corporate name change from Miles Inc. to Bayer Corp.
- 2) Previous labeling contained the following statement under the Protective Clothing Statement section:

“USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders and dip vat tank workers must wear a chemical resistant apron and face shield or goggles and a NIOSH/MSHA approved respiratory protection device.”

With the enclosed draft labeling, we are proposing to revise this statement using the statement required by the RED which includes the glove statement established for coumaphos in Supplement Three of PR Notice 93-7. The proposed statement reads as follows:

“Applicators and other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, shoes ~~plus socks~~.”

“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”

"Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Follow manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

- 3) On the enclosed draft labeling, we have deleted all recommendations for control of screwworms on cattle and horses by spray applications.
- 4) Previous labeling contained the following statement for cattle under the Remarks section for the Horn Flies and Lice use pattern:

"Repeat as necessary."

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

"Treat no more than six times per year. Do not make applications less than 10 days apart."

- 5) Previous labeling contained the following statement for cattle under the Remarks section for the Ticks use pattern:

"Repeat as necessary."

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

"Treat no more than six times per year. Do not make applications less than 10 days apart."

- 6) Previous labeling contained the following statement for lactating dairy cattle under the Remarks section for the Lice use pattern:

"Repeat as necessary."

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

"Treat no more than six times per year. Do not make applications less than 10 days apart."

- 7) Previous labeling contained the following statement for horses under the Remarks section for the Horn Flies and Lice use pattern:

“Repeat as necessary.”

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

“Treat no more than six times per year. Do not make applications less than 10 days apart.”

- 8) Previous labeling contained the following statement for horses under the Remarks section for the Ticks use pattern:

“Repeat as necessary.”

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

“Treat no more than six times per year. Do not make applications less than 10 days apart.”

- 9) Previous labeling contained the following statement for swine under the Remarks section for the Lice use pattern:

“Repeat as necessary.”

With the enclosed draft labeling, we are proposing to revise this verbiage in the following manner:

“Treat no more than six times per year. Do not make applications less than 10 days apart.”

- 10) The following section and statement has been added to the label under the Directions for Use in accordance with the RED:

“Entry Restriction: Do not contact treated animals until their coats are dry.”

- 11) The following statements have been added to the label under the Use Restrictions section in accordance with the RED:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

"Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc."

- 12) The following statements have been added to the label under the Environmental Hazards section in accordance with the RED:

"Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate."

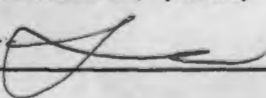
- 13) The following section and statements have been added to the label in accordance with the RED with the exception that the term "feed bunk" replaces "drinking cup" as specified on the RED because drinking cups are not used for cattle. In addition, the words "or drink" were added for clarity.

"Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment."

Please note, the proposed revisions in the use directions do not add any uses (animals or pests); do not increase any use rates; and are more restrictive than the currently registered use directions which permit "Repeat as necessary" applications.

As all, except one, of the proposed modifications in the enclosed labeling were Agency requested, and as none of the proposed modifications require data review, we anticipate ready Agency acceptance of the proposed labeling.


Included with this application are two completed and signed "Certification with Respect to Citation of Data" forms indicating the General Offer to Pay although all data cited in EPA's September, 1989 "Registration Standard (Second Round Review) for the Registration of Pesticide Products Containing Coumaphos as the Active Ingredient," are Bayer (formerly Miles, Mobay and Bayvet) data or public literature data.

REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.	
INCOMING CALL	<input checked="" type="checkbox"/>	VISITOR	DATE	11/24/95
OUTGOING CALL		CONGRESSIONAL	TIME OF CALL	
NAME AND ADDRESS OF CALLER OR VISITOR Terry McNamara Miles Inc. Box 350 Shawnee Mission KS			PHONE NO.	
			REGISTRATION ID NO. OR FILE SYMBOL 11536-115	
			DATE OF LATEST SUBMISSION 11/22/94	
BRIEF SUMMARY OF CONVERSATION Labels revisions per last letter by SED. <div style="text-align: right;">320/480637 38/</div>				
ACTION TAKEN OR RECOMMENDED Registrant will submit new labels, therefore current application (amendment) is superseded by new amendment .				
RECORDED BY (NAME) 			REFERRED TO (NAME)	

480637

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number 211551
	Application for Pesticide:		
	Section I		

1. Company/Product Number Miles Inc. / 11556-115	2. EPA Product Manager Mr. George T. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Miles Inc. / Co-Ral Livestock Insecticide Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Miles Inc. Agriculture Div., Animal Health Products P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

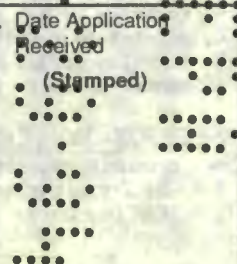
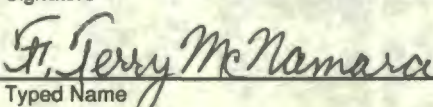
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.		If "Yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other (_____)			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name F. Terry McNamara		Title Biochemistry and Pesticide Registrations Manager	
		Telephone No. (Include Area Code) (913) 258-2588	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature 		3. Title Biochemistry and Pesticide Registrations Manager	
4. Typed Name F. Terry McNamara		5. Date November 22, 1994	

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III. (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV. (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States Environmental Protection Agency
Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicants Name and Address Miles Inc. Agriculture Division Animal Health Products P.O. Box 390 Shawnee Mission, KS 66201-0390	EPA File Symbol/Registration Number 11556-115
	Product Name Co-Ral Livestock Insecticide Spray
	Date of Application November 22, 1994

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

|| I am the original submitter*; or

|| I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☒ I am the original data submitter*; or

|| I have obtained the written permission of the original data submitter to cite that study*; or

b. || I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

|| All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

|| Those companies that have submitted the studies which I have cited (Selective method*).

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature <i>F. Terry McNamara</i>	Name and Title F. Terry McNamara Biochemistry and Pesticide Registrations Manager	Date November 22, 1994
---------------------------------------	--	---------------------------

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature <i>F. Terry McNamara</i>	Name and Title F. Terry McNamara Biochemistry and Pesticide Registrations Manager	Date November 22, 1994
---------------------------------------	--	---------------------------

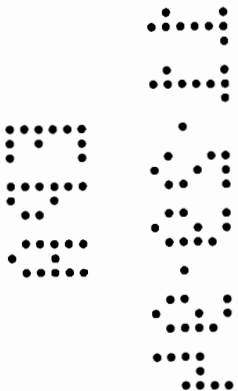
Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to 1.0 hours per response, including time for reviewing instructions, certifying the existence of the appropriate data, and completing and mailing this form. Send comments regarding the burden estimate or any other aspect of this certification process including suggestions for reducing the burden to:

Chief, Information Policy Branch, PM-223
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503





Certification with Respect to Citation of Data

Applicants Name and Address

Miles Inc.
Agriculture Division
Animal Health Products
P.O. Box 390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number

11556-115

Product Name

Co-Ral Livestock Insecticide Spray

Date of Application

November 22, 1994

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

|| I am the original submitter*; or

|| I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☒ I am the original data submitter*; or

|| I have obtained the written permission of the original data submitter to cite that study*; or

b. || I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

|| All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

|| Those companies that have submitted the studies which I have cited (Selective method*).

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

November 22, 1994

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

November 22, 1994

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to 1.0 hours per response, including time for reviewing instructions, certifying the existence of the appropriate data, and completing and mailing this form. Send comments regarding the burden estimate or any other aspect of this certification process including suggestions for reducing the burden to:

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Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503

2070-0060

ATTACHMENT FOR OPP #21151,
APPLICATION FOR PESTICIDE AMENDMENT

Enclosed for Agency acceptance are 5 copies of draft labeling, dated 10/19/94, for CO-RAL Livestock Insecticide Spray, EPA Reg. No. 11556-115. The most recent EPA stamped-accepted labeling for Co-Ral Livestock Insecticide Spray is dated 7/21/94.

The comments EPA forwarded to Miles accompanying the accepted labeling (dated 7/21/94) have been incorporated into the enclosed draft labeling:

- The EPA Registration Number for Co-Ral Livestock Insecticide is 11556-115.
- Under the Spray Treatments for screwworms for beef and non-lactating dairy cattle, the last sentence now reads, "Repeat as necessary but not more often than every 14 days."
- Under the Environmental Hazards Statement the following sentence was inserted as the second sentence in the paragraph, "Do not apply directly to any body of water." While this sentence appears correctly on the enclosed draft labeling, Final Printed Labeling was submitted to the Agency for review on 8/19/94, and this sentence appeared as the third (last) sentence in the paragraph. This error was discussed with Ms. Linda Arrington of your staff, and Ms. Arrington advised Miles to correct the label with the next printing of the labels and notify the Agency of the correction at that time.
- The statement, "Causes moderate eye irritation." was inserted as the third sentence, appearing before the statement, "Avoid contact with skin..."

- Following the IF ON SKIN statement, the phrase, “Get medical attention if irritation appears.” was added.

The enclosed draft labeling for the Co-Ral Livestock Insecticide Spray was modified to add flies as a pest under the Recommended Applications for lactating dairy cattle. The enclosed draft labeling differs from the most recent EPA stamped-accepted labeling in the following way:

- Recommended Applications was changed from, “Lactating Dairy Cattle: Lice” to, “Lactating Dairy Cattle: Lice, Flies.”

As provided for in the regulations, we request that the requirements for efficacy data be waived.

Included with this application are two completed and signed “Certification with Respect to Citation of Data” forms indicating the General Offer to Pay although all data cited in EPA’s September, 1989 “Registration Standard (Second Round Review) for the Reregistration of Pesticide Products Containing Coumaphos as the Active Ingredient,” are Miles (formerly Mobay and Bayvet) data or public literature data.

As this application for amended registration does not involve any review of data, we anticipate the Agency can act on this application expeditiously.

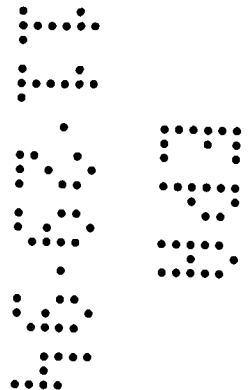
11/94
277

mg

Certified Mail No. 437 201 968

Document Processing Desk (AMEND)
Office of Pesticide Programs - H7504C
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Attachments: Application for Pesticide Amendment (OPP #211551)
5 copies of CO-RAL Livestock Insecticide Spray draft labeling
Certification with Respect to Citation of Data (2)



Reason to Issue: To add flies as a label claim
for lactating dairy cattle

Date: 10/19/94
Supersedes: 7/7/94
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

LIVESTOCK INSECTICIDE SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
Active Ingredient:	
O,O-Diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	5.8%
Inert Ingredients*:	<u>94.2%</u>
Total	100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb O,O-Diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-115

EPA Est. No. 11556-KS-1

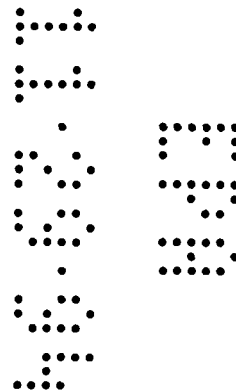
KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS: 1.892 L (0.50 gallon)

Miles Inc.
Agriculture Division
Animal Health Products
P.O. Box
Shawnee Mission, Kansas 66201 U.S.A.



Reason to Issue: To add flies as a label claim
for lactating dairy cattle

Date: 10/19/94
Supersedes: 7/7/94
Page 2 of 8

(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Causes moderate eye irritation. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water. Get medical attention if irritation appears.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Do not contaminate water when disposing of equipment washwater or rinsate.

Reason to Issue: To add flies as a label claim
for lactating dairy cattle

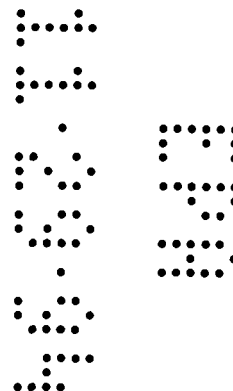
Date: 10/19/94
Supersedes: 7/7/94
Page 3 of 8

(Side Panel Continued)

LIMITED WARRANTY AND
LIMITATION OF DAMAGES

Miles Inc., Agriculture Division, warrants that this material conforms to the chemical description on the label. MILES INC. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Miles Inc. is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Miles Inc.



Reason to Issue: To add flies as a label claim
for lactating dairy cattle

Date: 10/19/94
Supersedes: 7/7/94
Page 4 of 8

(Side Panel)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Livestock Insecticide Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Livestock Insecticide Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Livestock Insecticide Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

PROTECTIVE CLOTHING STATEMENT

USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders must wear a chemical resistant apron and face shield or goggles and a NIOSH/MSHA approved respiratory protection device.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Livestock Insecticide Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

Reason to Issue: To add flies as a label claim
for lactating dairy cattle

Date: 10/19/94
Supersedes: 7/7/94
Page 5 of 8

(Side Panel Continued)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

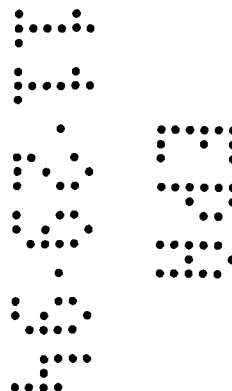
Do not apply as a spray at rates above 1 quart of Co-Ral Livestock Insecticide Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.



Reason to Issue: To add flies as a label claim
for lactating dairy cattle

Date: 10/19/94
Supersedes: 7/7/94
Page 6 of 8

(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY
CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Repeat as necessary.
	Ticks	4	10	
	Screwworms	8	20	SPRAY TREATMENT(S): Apply specified dosage as high pressure spray so as to wet the skin, not just the hair, of the animal. Repeat as necessary, but not more often than every 14 days.
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Repeat as necessary. No interval is required between treatment and slaughter or use of milk.

(Continued)

Reason to Issue: To add flies as a label claim
for lactating dairy cattle

Date: 10/19/94
Supersedes: 7/7/94
Page 7 of 8

(Back Panel Continued)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
	Ticks	4	10	Treat thoroughly all wounds and injuries. Repeat as necessary.
	Screwworms	8	20	

(Continued)

Reason to Issue: To add flies as a label claim
for lactating dairy cattle

Date: 10/19/94
Supersedes: 7/7/94
Page 8 of 8

(Back Panel Continued)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Repeat as necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO.

DATE OF ISSUANCE

11556-115

JUL 21 1991

TERM OF ISSUANCE

Until Reregistration

NAME OF PESTICIDE PRODUCT

Co-Ral Livestock Insecticide
Spray

NOTICE OF PESTICIDE: ☐ REGISTRATION
☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Miles, Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name, or to its use if it has been covered by others. This product is conditionally registered in accordance with

FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase, "EPA Registration No. 11556-115".
- b. Under Spray Treatments for screwworms for beef and non-lactating dairy cattle, revise the following statement: "Repeat as necessary but not more often than every 14 days."
- c. Under the Environmental Hazards Statement add the following statement as the second sentence in the paragraph:

Do not apply directly to any body of water.

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

- d. Add "**Causes moderate eye irritation.**" before the statement beginning "Avoid contact with skin..." in the precautionary hazards statement.
- e. Following the **IF ON SKIN** statement add,, "**Get medical attention if irritation appears.**"

3. Submit five copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

4. The Confidential Statement of Formula dated March 8, 1994 will not meet the label claim for the nominal concentration for the active ingredients. The upper and lower certified limits should be calculated as follows $N \pm 5\%N$ where N is the nominal concentration of the active ingredient. Refer the PR Notice 91-2 and 40 CFR 158.175 for guidance and revised the CSF to reflect the nominal concentration of the pure active ingredient.

5. The acute oral toxicity studies (MRIDs 428498-01 and 431025-01) were acceptable and assigned Toxicity Category II Guideline. A copy of the review is enclosed for your reference.

Please let us know your intentions with respect to Co-Ral ELI product under EPA Reg. No. 11556-23. Will this product replace Co-Ral ELI product?

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

cc: Dennis McNeilly, SRRD

(Front Panel)

Co-Ral®

(coumaphos)

LIVESTOCK INSECTICIDE SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUL 21 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
11532-115

Active Ingredient:

0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl)
phosphorothioate

5.8%

Inert Ingredients*:

94.2%
100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-XXX

EPA Est. No. 11556-KS-1

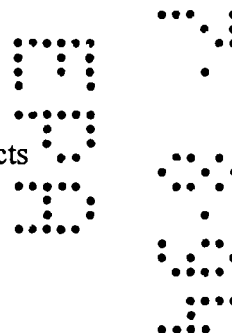
KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS ½ GALLON

Miles Inc., Agriculture Division, Animal Health Products
Shawnee Mission, Kansas 66201 U.S.A.



(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin: Remove contaminated clothing and wash affected areas with soap and water.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

ENVIRONMENTAL HAZARDS

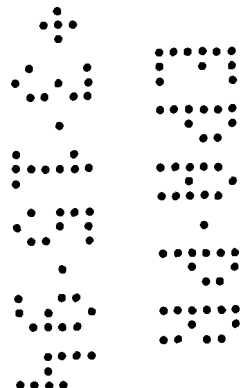
This pesticide is toxic to birds, fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate.

(Side Panel Continued)

LIMITED WARRANTY AND
LIMITATION OF DAMAGES

Miles Inc., Agriculture Division, warrants that this material conforms to the chemical description on the label. MILES INC. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Miles Inc. is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Miles Inc.



(Side Panel)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Livestock Insecticide Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Livestock Insecticide Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Livestock Insecticide Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

PROTECTIVE CLOTHING STATEMENT

USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders must wear a chemical resistant apron and face shield or goggles and a NIOSH/MSHA approved respiratory protection device.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Livestock Insecticide Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

(Side Panel Continued)

USE RESTRICTIONS

For external insecticidal use only on specified animals.

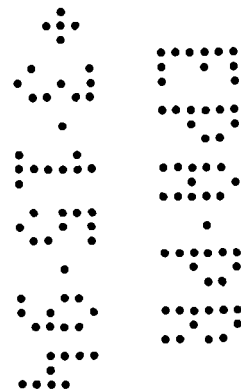
Do not apply as a spray at rates above 1 quart of Co-Ral Livestock Insecticide Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.



(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY
CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Repeat as necessary.
	Ticks	4	10	
	Screwworms	8	20	SPRAY TREATMENT(S): Apply specified dosage as high pressure spray so as to wet the skin, not just the hair, of the animal. Repeat as necessary.
Lactating Dairy Cattle	Lice	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Repeat as necessary. No interval is required between treatment and slaughter or use of milk.

(Continued)

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon). Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
(Not intended for slaughter)	Ticks	4	10	Treat thoroughly all wounds and injuries. Repeat as necessary.
	Screwworms	8	20	

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Repeat as necessary.

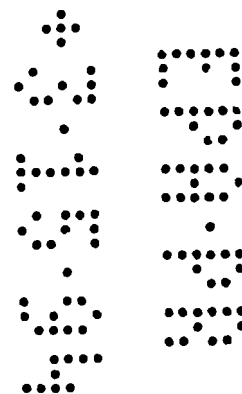
STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FIFRA
CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12356)

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. #: 11556-RRL; Co-Ral Livestock
Insecticide Spray

To: George Larocca, PM # 13 Attn: Linda Arrington
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: David L. Ritter, Toxicologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

DOR 6-9-94

THRU:: Thomas C. Ellwanger, Jr., Ph.D., Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

*Mary Waller
for T.E.
6/9/94*

Registrant: Miles Inc.
Agriculture Division
Animal Health Products
Box 390
Shawnee Mission KN 66201

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by Wt.</u>
O,O-Diethyl O-(3-chloro-4-methyl- 2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	6.15%
<u>Inert Ingredient(s):</u>	93.85%
Total	100.00%

Action Requested:

1. Review acute oral toxicity studies.
2. Comment on precautionary labeling.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Background:

Miles is submitting these two acute oral toxicity studies in rats in order to support a new formulation that has one half the AI of the original registration. The original product containing 11.6% AI was rated as a Restricted Use pesticide in the Registration Standard Second Round Review of September 1989 based on its acute oral toxicity (TOX Category I).

The proposed new formulation is a variation on #11556-23, Co-Ral Emulsifiable Livestock Insecticide. The registrant was informed in a meeting with HED on 11/29/90 that this was a new product and new acute oral toxicity data would be needed to support it. He will use the data developed for the original formulation (EPA Reg. # 11556-23) to support registration of the new formulation (EPA Reg. # 11556-RRL). See the Confidential attachment for a comparison of the two formulations.

1. Data Review:

The acute oral studies have been reviewed and the DERs are appended. MRID # 428498-01 showed an LD₅₀ of 395 mg/kg in females; TOX Category II. MRID # 431025-01 showed an LD₅₀ of 495 mg/kg in females, TOX Category II. Both studies are classified CORE Guideline.

These data results support removing the Restricted Use label provisions by moving the product from TOX category I to TOX Category II.

Additional acute data submitted in support of EPA Reg. # 11556-23 (11.6% AI) are being cited in support of the new registration. These were reviewed in the R. Zendzian memorandum of 11/17/82 which are summarized here:

Acute Toxicity Data Requirements (40 CFR §158.340).
Pesticide Assessment Guidelines, Subdivision F. Hazard Evaluation: Human and Domestic Animals. (1982; revised 1984).

<u>Data Required</u>	<u>MRID #</u>	<u>Toxicity Category</u>	<u>Classification</u>
Acute Oral (§81-1)	acc. # 248200	I	M
Acute Dermal (§81-2)	"	III	M
Acute Inhal. (§81-3)	"	III*	G
Eye Irr. (§81-4)	"	III	M
Dermal Irr. (§81-5)	"	III	M
Dermal Sens. (§81-6)	"	Non-Sens.	M

* An examination of the study (Mobay # 81-041-16) showed that the LC₅₀ for males was 1300 mg/m³; for females it was 795 mg/m³, placing the study in TOX category III (> 0.5 - 5.0 mg/l).

Recommendation(s):

1. Removal of the "Restricted Use" classification is appropriate based on a reduction in the amount of AI in the formulation from 11.6 % AI to 6.15% AI, and new acute oral toxicity data which support a TOX Category II (LD₅₀ between 50 mg/kg and 500 mg/kg in female rats).
2. According to HED this formulation is considered to be a new registration, and new acute oral data would be required.

Additional acute toxicity studies are not needed for the new formulation because data submitted in support of the original formulation likewise support the new registration. We have summarized this data base here and offer comments on the individual studies:

Current Toxicity Data Base for 11556-23

Acute Dermal (§81-2)	III	M	LD ₅₀ > 3000 mg/kg
Acute Inhal. (§81-3)	III	G	LC ₅₀ 0.795 mg/l
Eye Irr. (§81-4)	III	M	Cleared by day 7.
Dermal Irr. (§81-5)	III	M	" " "
Dermal Sens. (§81-6)	Non-Sens.	M	

Acute dermal study is not needed because the modest increase in percent [REDACTED] would not be expected to produce an LD₅₀ sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Acute inhalation study is not needed because the original HED TOX rating of TOX II was in error and should have been TOX III. Moreover, the LC₅₀ of 0.795 mg/l is on the low side of the TOX III range; a cut of 50% AI would not likely produce a TOX IV LC₅₀ rating. Moreover, registrant was not told this study would be needed at the HED meeting.

Eye irritation study is not required because irritation effects were reported to be most evident at day one. Thus, the modest increase in percent [REDACTED] would not be expected to produce an irritancy sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Dermal irritation study is not required because effects had vanished by day 3. Thus, the modest increase in percent [REDACTED] would not be

expected to produce an irritation index sufficiently low to change the TOX category. Moreover, registrant was not told this study would be needed at the HED meeting.

Dermal sensitization study is not needed because the components of the new formulation are the same as those in the original formulation. Moreover, registrant was not told this study would be needed at the HED meeting.

3. Precautionary Labeling Review:

Signal Word: Acceptable

Precautionary Statements:

After the sentence, "Avoid contact ... eyes.", insert the following sentence: "Causes moderate eye irritation".

Statements of Practical Treatment:

If on Skin: Add the following: "Get medical attention.

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

Product Manager (PM): 13 EPA Reg. No.: 11556-RRL

Reviewer: David L. Ritter, Toxicologist 0425-2-94

MRID No.: 428498-01

Testing Laboratory: Miles Inc.
Toxicology
17745 South Metcalf
Stillwell, KN 66085-9104

Title Of Report: Acute Oral Toxicity Study with Coumaphos 6.15%
(CO-RAL^R) in Rats.

Date of Report: 11/2/92

Lab. No.: 92-012-PL (Miles # 103294)

Author(s): A.B. Astroff & L.L. Hagen

Species: Sprague Dawley rat Sex: 20M + 20F

Wt.: M: 174 -211 gm; F: 160 - 186 gm

Source: Sasco, Inc., St. Louis, MO.

Test Material: CO-RAL Livesock Insecticide Spray (LIS)

Dosage: See below.

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

LD₅₀ Males = 1477 mg/kg
LD₅₀ Females = 395 mg/kg

TOX Category: II; LD₅₀ between 50 mg/kg and 500 mg/kg
(females).

Core Classification: Guideline

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article Administration:

Test Article was administered by gavage in 0.5% aqueous methyl cellulose to groups of 5M or 5F each at doses listed here:

<u>Males mg/kg</u>	<u>Females mg/kg</u>
0	0
889	89
1870	271
2870	471

Animals were observed twice daily on weekdays and once daily on weekends for fourteen days for mortality and signs of toxicity.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Body weight gain decreased from day 0 thru 7 with recovery apparent by day 14 in the survivors.

Signs of toxicity included ataxia, tremors, torpor, fasciculations, salivation and staining.

REPORTED MORTALITY

DOSAGE MG/KG	MALES No. Dead/No. Exposed	FEMALES No. Dead/No. Exposed	COMBINED No. Dead/No. Exposed
0.0	0/5	0/5	0/10
889	0/5		0/5
1870	4/5		4/5
2870	5/5		5/5
89		0/5	0/5
271		0/5	0/5
471		4/5	4/5

LD₅₀ Males = 1477 mg/kg

LD₅₀ Females = 395 mg/kg

Necropsy revealed no lesions attributable to treatment.

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

Product Manager (PM): 13 EPA Reg. No.: 11556-RRL

Reviewer: David L. Ritter, Toxicologist *DLR 5-2-94*

MRID No.: 431025-01

Testing Laboratory: Miles Inc.
Toxicology
17745 South Metcalf
Stillwell, KN 66085-9104

Title Of Report: Acute Oral Toxicity Study with CO-RAL^R Livestock
Insecticide Spray in Rats.

Date of Report: 1/25/94

Lab. No.: 93-012-WT (Miles # 103294-02)

Author(s): M.A. Zorbas

Species: Sprague Dawley rat Sex: 40M + 40F

Wt.: M: 169 -228 gm; F: 145 - 180 gm

Source: Sasco, Inc., Omaha NB.

Test Material: CO-RAL Livesock Insecticide Spray

Dosage: See below.

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

LD₅₀ Males = 1011 mg/kg
LD₅₀ Females = 495 mg/kg

TOX Category: II; LD₅₀ between 50 mg/kg and 500 mg/kg
(females).

Core Classification: Guideline

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article Administration:

Animals were fasted overnight before dosing. Test Article was administered by gavage in 0.5% methyl cellulose and 0.4% Tween 80 in deionized water to groups of 5M or 5F each at doses listed here:

<u>Males mg/kg</u>	<u>Females mg/kg</u>
0	0
486	94.3
627	270
946	486
1490	571
1930	686
2800	735

Animals were observed twice daily on weekdays and once daily on weekends for fourteen days for mortality and signs of toxicity.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Body weight gain increased from day 0 through 14 in the male survivors in the 486, 627 and 946 mg/kg groups. Surviving males in the 1490 mg/kg group lost weight initially but regained some weight in the later days of the observation period. This pattern was repeated in the females.

Signs of toxicity included ataxia, torpor, fasciculations, salivation and oral, nasal and ano-genital staining. Convulsions in females was also reported.

REPORTED MORTALITY

DOSAGE MG/KG	MALES No. Dead/No. Exposed	DOSAGE N MG/KG	FEMALES No. Dead/No. Exposed
0.0	0/10	0.0	0/10
486	0/5	94.6	0/5
627	2/5	270	0/5
946	2/5	486	1/5
1490	4/5	571	5/5
1930	5/5	686	5/5
2800	5/5	735	5/5

LD₅₀ Males = 1011 mg/kg

LD₅₀ Females = 495 mg/kg

Necropsy revealed no lesions attributable to treatment.

ACUTE TOX ONE-LINER

1. PC CODE: 036501; Coumaphos
2. CURRENT DATE: 4/22/94
3. TEST MATERIAL: Co-Ral Livestock Insecticide Spray
4. EPA Reg. #: 11556-RRL

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Acute oral/Rat/Miles /92-012-PL/11/2/92	428498-01	LD ₅₀ M = 1477 mg/kg LD ₅₀ F = 395 mg/kg	II	G
Acute oral/Rat/Miles /92-012-PL/11/2/92	431025-01	LD ₅₀ M = 1011 mg/kg LD ₅₀ F = 495 mg/kg	II	G

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary

042 5-2-94

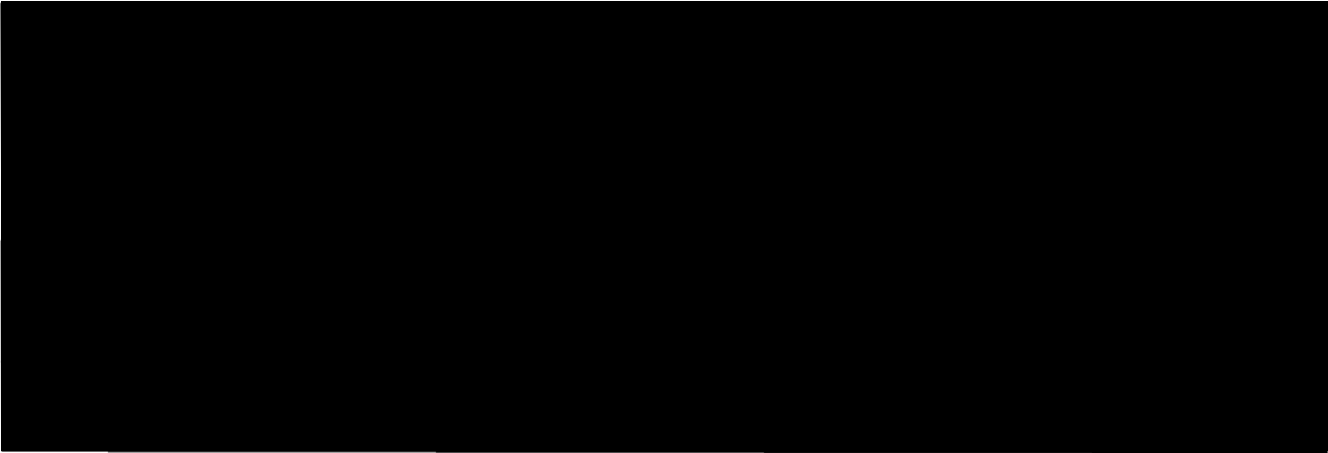
CONFIDENTIAL ATTACHMENT

EPA Reg. # 11556-RRL; Co-Ral Livestock Insecticide Spray
Discussion of Inert Ingredients.

The registrant is basing support for the subject formulation on toxicity data obtained from the previous formula. Specifically, he is diluting the AI (coumaphos) at 11.6 % down to 6.15% and making up the difference with [REDACTED]

[REDACTED] as follows:

<u>Component</u>	<u>EPA Reg.# 11556-23</u>	<u>EPA Reg.# 11556-RRL</u>
Coumaphos Technical	11.9%	6.15%



Agriculture Division

Animal Health Products

Miles Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 631-4800
Telex: 437269 Miles AHD

March 29, 1994

Mr. George LaRocca

Product Manager 13
Insecticide-Rodenticide Branch
Registration Division H7505C
Office of Pesticide Programs
Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460

Subject: Co-Ral Livestock Insecticide Spray; EPA File Symbol 11556-RRL

Dear Mr. LaRocca:

With regard to the subject application, dated 6/30/93, we are requesting that the Registration Division expedite the review of the 81-1 acute oral toxicity data for this product. The review of these data is the only item preventing the registration of this product.

Commonly we do not petition for special expedited review, but this is an unusual situation which warrants your attention and should justify expedited review.

Briefly there are at least three reasons for expedited review.

1. Availability of a Less Toxic or "Safer" Product.

Co-Ral Livestock Insecticide Spray, EPA File Symbol 11556-RRL (hereafter referred to as the LIS product), is the same formulation as Miles currently registered product Co-Ral Emulsifiable Livestock Insecticide, EPA Reg. No. 11556-23 (hereafter referred to as the ELI product), with only one exception. The proposed new product (LIS) contains approximately one-half the active ingredient present in the 11556-23 product (ELI); in the LIS product the dilution solvents replace half of the active ingredient resulting in simply a one-half strength, diluted ELI product.

Please note, the more toxic product (ELI) was first registered on 5/24/64 as Reg. No. 3125-162. This product was not designed for home or casual animal use; it is not labeled for pet use such as for dogs or cats; it is labeled only for use on cattle, swine and horses. The product was designed for and has been used by livestock producers. This product was safely used by livestock producers for more than 25 years when the Agency's 1989 "Registration Standard (Second Round Review) for the Reregistration of Pesticide Products Containing Coumaphos as the Active Ingredient" (hereafter referred to as the Guidance Document) required the reclassification of the ELI product (11.6% active ingredient) and our Co-Ral Flowable Insecticide product (42% active ingredient), EPA Reg. No. 1156-98, as Restricted Use Pesticides because of the high acute oral toxicity of these two formulations. The Guidance Document also required much additional restrictive labeling to mitigate any possible acute toxicity hazards to users.

With regard to the Restricted Use Classification, Miles formally requested the Agency's reason for such reclassification. In response, the Agency's 2/12/91 Toxicology Branch memo states the following:

11.6% EC Formulation

In the toxicology review of R. Zendzian dated November 26, 1982 on the report of the acute oral toxicity of the 11.6% EC formulation (Bayvet Report No. 72228, dated December 15, 1981), the oral LD₅₀ in female rats was reported to be 50 mg/kg. An end-use product with an Oral LD₅₀ of 50 mg/kg or less will be considered for restricted use [40 CFR 152.170 (a) (2) (i)]. This is the reason why the 11.6% EC formulation requires a restricted-use classification.

Although the ELI product was only borderline Toxicity Category I by acute oral exposure, and although the many previous years of safe use indicate acute oral exposure to livestock producers is negligible, Miles relabeled the ELI product as a Restricted Use Product.

Just as in the previous 25 years without the restrictive labeling, the recent relabeled ELI product has been safely used by livestock producers.

With the LIS product we have lowered the active ingredient concentration by an approximate factor of two. This product is consequently less orally toxic; the acute oral LD₅₀ values for the LIS product are 1011 mg/kg for male rats and 495 mg/kg for female rats.

Also, even though the ELI product was safely used for more than 25 years without the more restrictive labeling for users, with our application for the diluted, less toxic, LIS product, we have included all the restricted protective clothing language, etc. on the more toxic ELI product.

In short, although the ELI product has been used safely by livestock producers for nearly 30 years, the proposed LIS product with less active ingredient and the more restrictive language of the LIS product will provide livestock producers with a "safer," less toxic product.

2. Amount of Data to be Reviewed.

To support our application, Miles submitted the appropriate product chemistry data, which has already been reviewed, and one 81-1 acute oral toxicity study. Acute oral toxicity data are the only remaining data needing expedited review for registration.

As a point of clarification, two supplements to the 81-1 acute oral toxicity study (Miles Report No. 103294, EPA MRID No. 42849801) were submitted. In explanation, after the initial study Miles found a GLP violation and submitted a corrected GLP statement as an addendum - Miles Report No. 103294-1, EPA MRID No. 43057401, and although Miles believes the values from the initial study are scientifically sound, Miles conducted another 81-1 study under GLP. The results of this study are Miles Report No. 103294-2, EPA MRID No. 43102501, and these results confirm the results from the initial study.

In short, the only data needing to be reviewed for the registration of the LIS are 81-1 acute oral toxicity data. There are results from one non-GLP study (EPA MRID No. 42849801) and a GLP Study (EPA No. 43102501) which are similar.

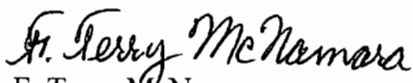
3. Timeliness.

As noted above, Miles submitted for the registration of this product on 6/30/93. In follow-up discussions with your staff, we have been advised that these acute oral toxicity data will not be assigned for review for at least another year. We were advised that because our proposed registration is not a "me-too" registration nor any other type of high priority registration, our registration action is a low priority. Other proposed registration actions submitted after our application are being assigned a higher priority and are and will be reviewed before ours. Depending upon incoming submissions, conceivably after even 18 months in line, our data may be no closer to being reviewed than when it was first submitted.

In conclusion, we respectfully request that the Registration Division expedite the review of the 81-1 acute oral toxicity data for the LIS product, EPA File Symbol 11556-RRL. The review of the acute oral toxicity data should not require significant review efforts, and the end result will be a less toxic product for livestock producers.

If you have any questions regarding this submission, please call me at (913) 268-2588.

Sincerely,

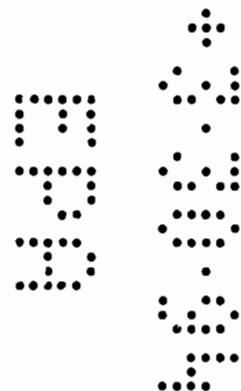


F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

FTM/lt

cc: Ms. Susan Lewis, Chief
Insecticide-Rodenticide Branch H7505C

Ms. Linda G. Arrington
Product Team 13, H7505C



Federal Express

July 7, 1994

Ms. Linda Arrington
Product Team 13
Registration Division H7505C
U.S. Environmental Protection Agency
Room 266A Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Miles Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 631-4800
Telex 437269 Miles AHD

Subject: Co-Ral Livestock Insecticide Spray; EPA File Symbol 11556-RRL

Dear Ms. Arrington:

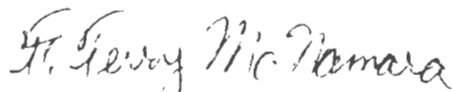
As we discussed by phone, enclosed are 5 copies of the first page of draft labeling for the subject product. The only difference between the enclosed first page and the first page of the draft labeling submitted 3/8/94 is in the ingredients statement.

Specifically, the first page of the 3/8/94 submitted draft labeling (which is dated 3/3/94) showed the amount of active ingredient to be 6.15%, and the amount of inert ingredients to be 93.85%. On the enclosed, revised page one, the amount of active ingredient is 5.8%, and the amount of inert ingredients to be 94.2%. This is the only difference between these two pages.

Please substitute the enclosed, revised page 1 for the page 1 of our 3/3/94 draft labeling, and use this for your label review. We are not proposing any changes in the remaining pages of the draft labeling dated 3/3/94.

If you have any questions on this matter or anything else regarding this proposed registration, please call me at (913) 268-2588.

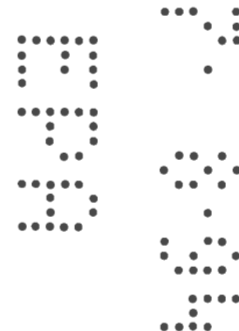
Sincerely,



F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

FTM/lt

Enclosure: Revised Page (5 copies)



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A)		United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Application for Pesticide:	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number <div style="font-size: 1.5em; color: red;">188393</div>

Section I

1. Company/Product Number 11556-RRL	2. EPA Product Manager Mr. George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Miles/Co-Ral Livestock Insecticide Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Miles Inc. Agriculture Division, Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - explain below.
--	--

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See Attachment

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Unit Package wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Other (_____) <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name F. Terry McNamara	Title Biochemistry and Pesticide Registrations Manager	Telephone No. (Include Area Code) (913) 268-2588
Certification		
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title Biochemistry and Pesticide Registrations Manager	
4. Typed Name F. Terry McNamara	5. Date 3/8/94	
6. Date Application Received (Stamped)		

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)1;
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Application for Pesticide

OPP #188393

Explanation:

On 6/30/93 Miles applied for the registration of Co-Ral Livestock Insecticide Spray, EPA File Symbol 11556-RRL. This submission is to address two items in the 8/17/93 product chemistry review and to provide revised labeling.

With regard to the labeling, enclosed are 5 copies of draft labeling dated 3/3/94. The enclosed draft labeling is identical to the previously submitted draft labeling (dated 6/29/93) with only two exceptions. First, on the enclosed draft labeling the percentages of active ingredient and inert ingredients have been revised to better reflect the Agency's desire for nominal percentages (discussed in detail later).

The second change on the enclosed draft labeling from that previously submitted is simply a rearrangement of the order of portions of the label with no basic text changes.

Specifically, the earlier draft labeling contained a front panel, a side panel with the Precautionary Statement, Storage and Disposal, and Protective Clothing Statement, and a back panel consisting of the Directions for Use, Recommended Applications, Use Restrictions and a warranty statement. In the enclosed draft labeling, the order of these items has been arranged in a more appropriate manner. In the enclosed labeling, the front panel is identical to that of the previous labeling (with the above noted change in nominal concentration). In the enclosed labeling, one side panel contains the Precautionary Statements and the warranty statement, and the other side panel begins the Directions for Use. This side panel contains general information followed by the Protective Clothing Statement and Use Restrictions (one word was changed in this section - from the word "above-specified" animals to the more appropriate word "specified" animals). The back panel of the enclosed labeling contains the Recommended Application tables and the Storage and Disposal section.

Again, the enclosed labeling text is identical to that previously submitted except for the one word noted above, and we have rearranged sections in order to provide a better label. For example, in the enclosed Directions for Use, the Protective Clothing Statement and Use Restrictions precede the Recommended Applications, and the Storage and Disposal section is at the end of the Directions for Use.

In response to the 8/17/93 product chemistry review, there are two items deserving comment.

The second item - item 4. on page 2 - is easier to address. The Material Safety Data Sheet (MSDS) and CAS Registry Number are requested for the inert ingredient

_____ was included as pp. 54-58 in the Confidential Appendix for Miles Report No. 74426, which has been assigned EPA MRID No. 42874501. These data were submitted with our 6/30/93 application for registration. Also, this same inert ingredient is contained in our Co-Ral Emulsifiable Livestock Insecticide product, EPA Reg. No. 11556-23, which is currently registered for the same uses proposed for the EPA File Symbol 11556-RRL product.

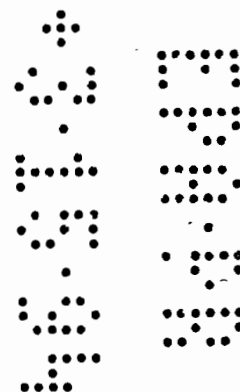
The first item in the 8/17/93 product chemistry review cannot be as succinctly addressed. The review correctly notes that the label claim for active ingredient in the proposed product (EPA File Symbol 11556-RRL) is 5.8%, and using a purity of 90% for Coumaphos Technical, an active ingredient concentration of 5.54% can be calculated which is below the declared label claim of 5.8%.

On this item, we have the following somewhat "administrative" comments. The formulation will be manufactured in the previously proposed manner. The enclosed draft labeling has a declared percentage of 6.15% active ingredient instead of 5.8%. (Please note, the formulation used in the toxicology studies, EPA MRID Nos. 42849801, 43057401 and 43102501, contained 6.15% active ingredient.) Also, enclosed is a revised Confidential Statement of Formula (CSF) for the proposed product. This CSF contains the ingredients in terms of a 1000 kg batch for ease of calculation. The percentages by weight in column 13b have been adjusted, and the proposed certified limits for one inert ingredient have been revised.

When calculating the amount of active ingredient in the product based on the amount of active ingredient in Coumaphos Technical, EPA Reg. No. 11556-11, a value of 96% active ingredient should be used instead of 90%. In explanation, the current Coumaphos Technical has a label claim of only 90%. This value was a "historical" lower limit. New product chemistry data were required under reregistration. Based on these data (EPA MRID No. 42675003, reviewed by the Agency - 7/28/93 Chemistry Branch Reregistration Support memo and the corresponding 5/10/93 Dynamac review) and as mandated for compliance with the Agency's new nominal concentration policy (PR Notice 91-2), on 10/27/93 Miles submitted for Agency acceptance a revised label claim of 96% active ingredient for Coumaphos Technical, EPA Reg. No. 1156-11. To date, Miles has not received any response from the Agency on this action.

Although no new data are being submitted, enclosed are 2 completed "Certification with Respect to Citation of Data" forms indicating the General Offer to Pay although all data cited in EPA's September, 1989 "Registration Standard (Second Round Review) for the Reregistration of Pesticide Products Containing Coumaphos as the Active Ingredient" are Miles (formerly Mobay and Bayvet) data or are public literature data.

In summary, enclosed with this application is draft labeling which better reflects a nominal concentration, but otherwise contains the same text in a more appropriate order. Also enclosed is a revised CSF.



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

FEB 3 1994

MILES INC.
AGRIC.DIV.-ANIMAL HEALTH PROD.
BOX 390
SHAWNEE MISSION, KS 662010390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/28/94. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Agriculture Division

Animal Health Products

January 25, 1994

Mr. George LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division H7505C
Office of Pesticide Programs
Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460

Miles Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 631-4800
Telex: 437269 Miles AHD

Subject: Co-Ral Livestock Insecticide Spray; EPA File Symbol 11556-RRL

Dear Mr. LaRocca:

With regard to the subject application, dated 6/30/93, we submitted an acute oral toxicity report entitled "Acute Oral Toxicity Study with Coumaphos 6.15% (Co-Ral) in Rats," Miles Report No. 103294, EPA MRID No. 42849801. On 12/8/93 we submitted a supplement to this report, and EPA MRID No. 43057401 was assigned to this supplement. This supplement was to amend the GLP Compliance Statement for this study because we concluded that it does not comply with the GLP requirements of 40 CFR Part 160. Nevertheless, we believe the data to be reliable.

Enclosed are three copies of another supplement to this report. This new supplement contains additional data from a new acute oral study conducted under GLP. The results of this new GLP study simply confirm the results from the initial study.

The enclosed supplement, Miles Report No. 103294-2, is entitled "Acute Oral Toxicity Study with Co-Ral® Livestock Insecticide Spray in Rats."

If you have any questions regarding this submission, please call me at (913) 268-2588.

Sincerely,

F. Terry McNamara /lt

F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

FTM/lt

Enclosure: Supplement Report (3)

Transmittal Document

1. Name and Address of Submitter

Miles Inc.
Agriculture Division
Animal Health Products
Box 390
Shawnee Mission, Kansas 66201

F. Terry McNamara/lt

F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager
(913) 268-2588

2. Regulatory Action in Which this Package is Submitted

Data submitted to support the registration of Co-Ral Livestock Insecticide Spray
EPA File Symbol 11556-RRL

3. Transmittal Date

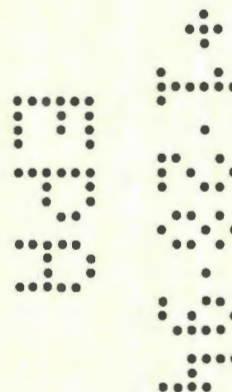
January 25, 1994

4. List of Submitted Studies:

MRID No. Volume

43102501 1 -

"Acute Oral Toxicity Study with Co-Ral®
Livestock Insecticide Spray in Rats; Supplement 2,"
EPA Guideline No. 81-1, Miles Report No. 103294-
2, M. A. Zorbas, 30 p.





United States Environmental Protection Agency
Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicants Name and Address

Miles Inc.
Agriculture Division
Animal Health Products
PO Box 390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number

11556-RRL

Product Name

Co-Ral Livestock Insecticide Spray

Date of Application

3/8/94

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

|| I am the original submitter*; or

|| I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☒ I am the original data submitter*; or

|| I have obtained the written permission of the original data submitter to cite that study*; or

b. || I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☒ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

|| Those companies that have submitted the studies which I have cited (Selective method*).

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

3/8/94

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

3/8/94



Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to 1.0 hours per response, including time for reviewing instructions, certifying the existence of the appropriate data, and completing and mailing this form. Send comments regarding the burden estimate or any other aspect of this certification process including suggestions for reducing the burden to:

Chief, Information Policy Branch, PM-223
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503



United States Environmental Protection Agency
Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicants Name and Address

Miles Inc.
Agriculture Division
Animal Health Products
PO Box 390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number

11556-RRL

Product Name

Co-Ral Livestock Insecticide Spray

Date of Application

3/8/94

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

☐ I am the original submitter*; or

☐ I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☒ I am the original data submitter*; or

☐ I have obtained the written permission of the original data submitter to cite that study*; or

b. ☐ I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☒ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

☐ Those companies that have submitted the studies which I have cited (Selective method*).

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

3/8/94

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

3/8/94

324

Attachment for OPP #188386, Application for Pesticide

With this application, the enclosed data and the enclosed labeling, we are requesting the registration of Co-Ral Livestock Insecticide Spray, EPA Reg No. 11556-XXX. Five copies of the proposed labeling, dated 6/29/93 are enclosed.

Please note, Miles has a similar product - Co-Ral Emulsifiable Livestock Insecticide, EPA Registration No. 11556-23- currently registered. When EPA issued the "Registration Standard (Second Round Review) for the Reregistration of Pesticide Products Containing Coumaphos as the Active Ingredient" (hereafter referred to as the "Guidance Document") in September, 1989, the Agency classified this product (11.6% active ingredient) and our Co-Ral Flowable Insecticide product (42% active ingredient), EPA Reg. No. 11556-98, as Restricted Use Pesticides because of the high acute oral toxicity of these two formulations.

Miles requested additional explanation on these reclassifications. In a November 29, 1990 meeting with the Agency (where this topic and other coumaphos topics were discussed; a copy of the attendance sheet is enclosed). The Agency responded (and a copy of an EPA 2/12/91 Toxicology Branch memo on this subject is also enclosed) that the acute oral toxicity of the 11.6% formulation had an oral LD₅₀ of 50 mg/kg. Consequently, the Toxicology Branch memo states

"An end-use product with an oral LD₅₀ of 50 mg/kg or less will be considered for restricted use [40 CFR 152.170 (a) (2) (i)]. This is the reason why the 11.6% EC formulation requires a restricted-use classification."

In this 11/29/90 meeting, Miles related that as the acute oral toxicity is the only "trigger" for the restricted use classification, if a more dilute, less acutely toxic formulation was developed then the restricted use classification would not be necessary. The Agency responded that this more dilute formulation would be considered a new product, and acute oral toxicity data would be necessary.

Accordingly, this application is for a product which is very similar to Co-Ral Emulsifiable Livestock Insecticide (ELI). The proposed new product contains only one-half (5.8%) of the active ingredient in ELI (11.6%); the 5.8% active ingredient no longer in the new, dilute product has been replaced by an additional 5.8% of one of the inert ingredients (See product chemistry data and discussion below). This new dilute product is less acutely toxic and does not meet the 50 mg/kg acute oral LD₅₀ trigger for restricted use classification.

Product Chemistry. Enclosed is a Confidential Statement of Formula (CSF) for this proposed product. Please note, this CSF contains qualitatively, the same components as the CSF for the ELI (EPA Reg. No. 11556-23). The most recent CSF for the ELI product is dated 1/17/90, was submitted to the Agency on 1/29/90, and was accepted by the Agency on 10/23/91 along with revised labeling for ELI, Co-Ral Cattle Pour-On (EPA Reg. No. 11556-25), and Co-Ral KRS Spray Foam Insecticide (EPA Reg. No. 11556-40) and the CSF's for the 11556-25 and 11556-40 products.

As shown in the enclosed CSF, quantitatively, the formulation for the new product is the same as the formulation for the ELI product with only one exception. The new formulation contains 5.8% less active ingredient and 5.8% more [REDACTED]

The product chemistry data for the new product are enclosed as Miles Report No. 74426, entitled "Product Chemistry of Co-Ral Livestock Insecticide Spray (LIS) ½ lb/gal."

Acute Toxicity. As cited above, Miles has conducted an acute oral toxicity study with the proposed new product, and copies of these results - Miles Report No. 103294, entitled "Acute Oral Toxicity Study with Coumaphos 6.15% (Co-Ral) in Rats" - are enclosed. The acute oral LD₅₀ was 1477 mg/kg for males and 395 mg/kg for females.

With regard to the other acute toxicity data requirements, we cite and will accept the acute toxicity values for the ELI formulation which contains 5.8% more active ingredient and 5.8% less [REDACTED] than the new product.

Specifically, the acute toxicity guidelines and EPA MRID Nos. for the corresponding data for the ELI formulation are

EPA Guideline No.	EPA MRID No.
81-2	00112833
81-3	00112836
81-4	00112834
81-5	00112835
81-6	00112837

Also please note, the Agency has reviewed all of these ELI acute toxicity studies and found them to be adequate (see p. 77 of the Guidance Document which lists the acute toxicity data for the 11.6% EC formulation).

Efficacy. As provided for in the regulations, we request that the requirements for efficacy data be waived.

Labeling. The enclosed draft labeling for the proposed product is based upon the most recently accepted labeling (Agency 10/23/91 letter) for Co-Ral Emulsifiable Livestock Insecticide, EPA Reg. No. 11556-23.

Briefly, the proposed labeling does not include restricted use classification for the reasons previously discussed. The signal word and Hazards to Humans and Domestic Animals language are consistent with the Toxicity Category II (oral and inhalation) of this product.

The Statements of Practical Treatment, Environmental Hazards and Storage and Disposal language are identical to that for the 11556-23 product.

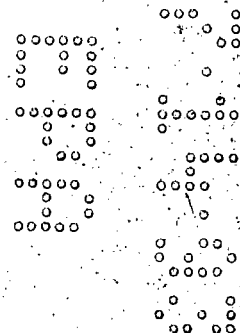
The protective clothing statement is also identical with only one exception. The phrase "and dip tank workers" has been deleted because the proposed product does not contain any dip vat uses.

The Directions for Use in the enclosed labeling are very similar to those currently accepted by the Agency for the ELI (EPA Reg. No. 11556-23) product.

For example, the enclosed draft labeling contains the same use restrictions.

All of the uses on the draft labeling are already on the ELI labeling. Moreover, the use rates on the draft labeling are equivalent in terms of active ingredient to the use rates on the ELI labeling. To reflect the fact that the new product contains only one-half the active ingredient contained in the ELI formulation, the enclosed draft labeling contains different dilution directions. Generally the ELI formulation use directions require "X" quarts of ELI to be used to prepare 100 gallons of spray. The enclosed corresponding use directions on the enclosed labeling require "X" quarts of the new product to be used to prepare 50 gallons of spray.

Also, the enclosed labeling contains an additional use directions column for the preparation of an equivalent (in terms of active ingredient) smaller volume of spray - 4 gallons.



As a specific example, the current ELI labeling specifies 4 quarts diluted to 100 gallons for spray treatment of ticks on beef and non-lactating dairy cattle. The enclosed labeling requires 4 quarts diluted to 50 gallons for the same use. Also, as there are 128 ounces per gallon, or 4 quarts, this use rate is 128 ounces per 50 gallons of spray. Or, in terms of ounces per gallons of spray, the use rate is

$$(128 \text{ ounces}) \left(\frac{1}{50 \text{ gallons}} \right) = 2.56 \text{ oz/gallon}$$

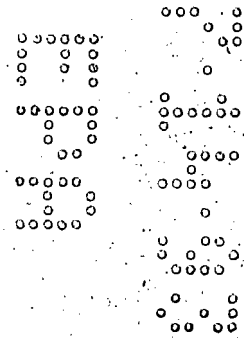
Therefore, the ounces of formulation to prepare 4 gallons of spray equals (4) (2.56 oz/gal) or 10.2 ounces, and the proposed labeling recommends 10 ounces of the new formulation to prepare 4 gallons of spray.

The enclosed labeling does not include the directions for use against grubs, which are in the ELI use directions.

Child Resistant Packaging. This proposed product will not be distributed and sold in child-resistant packaging because this product does not meet the use criterion of 40 CFR 157.22 (b).

FIFRA Section 3 (c) (1) (F) Data Compensation. Included with this application are two completed and signed "Certification with Respect to Citation of Data" forms indicating the General Offer to Pay although all data cited in EPA's September, 1989 "Registration Standard (Second Round Review) for the Reregistration of Pesticide Products Containing Coumaphos as the Active Ingredient," are Miles (formerly Mobay and Bayvet) data or public literature data.

Summary. Enclosed is an application for the registration of a new formulation of coumaphos. This formulation is simply a diluted formulation of Co-Ral Emulsifiable Livestock Insecticide, EPA Reg. No. 11556-23. Moreover, the proposed uses for the new formulation are the same uses (except grub use have been deleted) at the equivalent active ingredient use rates of the 11556-23 product.



Superseded by 3/3/94 label

Reason to Issue: To propose registration
of a new product

Date: 6/29/93
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

LIVESTOCK INSECTICIDE SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

Active Ingredient:

0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl)
phosphorothioate

5.8%

Inert Ingredients*:

94.2%
100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-XXX

EPA Est. No. 11556-KS-1

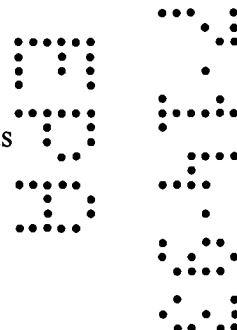
KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS ½ GALLON

Miles Inc., Agriculture Division, Animal Health Products
Shawnee Mission, Kansas 66201 U.S.A.



(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

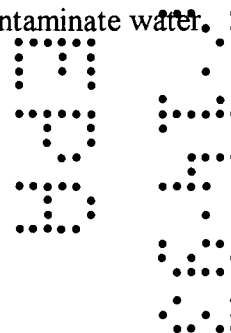
If on skin: Remove contaminated clothing and wash affected areas with soap and water.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate.



(Side Panel)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

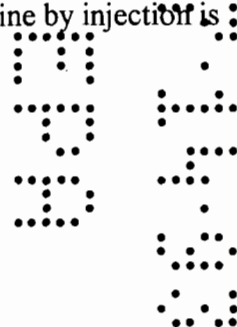
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PROTECTIVE CLOTHING STATEMENT

USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders must wear a chemical resistant apron and face shield or goggles and a NIOSH/MSHA approved respiratory protection device.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Livestock Insecticide Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.



(Back Panel)

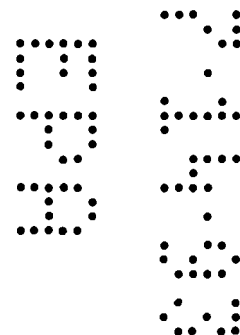
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Livestock Insecticide Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Livestock Insecticide Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Livestock Insecticide Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.



(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY
CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Repeat as necessary.
	Ticks	4	10	
	Screwworms	8	20	SPRAY TREATMENT(S): Apply specified dosage as high pressure spray so as to wet the skin, not just the hair, of the animal. Repeat as necessary.
Lactating Dairy Cattle	Lice	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Repeat as necessary. No interval is required between treatment and slaughter or use of milk.

(Continued)

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¼ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
(Not intended for slaughter)	Ticks	4	10	Treat thoroughly all wounds and injuries. Repeat as necessary.
	Screwworms	8	20	

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Repeat as necessary.

USE RESTRICTIONS

For external insecticidal use only on above-specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Livestock Insecticide Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

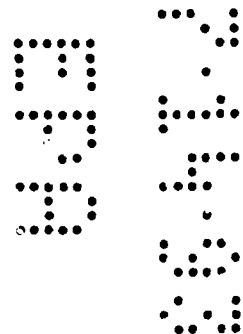
Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

**LIMITED WARRANTY AND
LIMITATION OF DAMAGES**

Miles Inc., Agriculture Division, warrants that this material conforms to the chemical description on the label. MILES INC. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Miles Inc. is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Miles Inc.



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

DEC 27 1993

MILES INC.
AGRIC.DIV.-ANIMAL HEALTH PROD.
BOX 390
SHAWNEE MISSION, KS 662010390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 12/15/93. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Agriculture Division

Animal Health Products

Miles Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 631-4800
Telex: 437269 Miles AHD

Certified Mail #P679 214 091

December 8, 1993

Mr. George LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division H7505C
Office of Pesticide Programs
Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460

430574- 00

Subject: Co-Ral Livestock Insecticide Spray; EPA File Symbol 11556-RRL

Dear Mr. LaRocca:

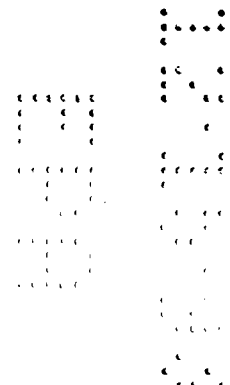
With regard to the subject application, dated 6/30/93, we submitted an acute oral toxicity report entitled "Acute Oral Toxicity Study with Coumaphos 6.15% (Co-Ral) in Rats," Miles Report No. 103294, EPA MRID No. 42849801. Enclosed are copies (3) of a supplement to this report entitled "Acute Oral Toxicity Study with Coumaphos 6.15% (Co-Ral) in Rats." This supplement is to amend the GLP Compliance Statement for this study because we have concluded that it does not comply with the GLP requirements of 40 CFR Part 160. Nevertheless, we believe the data to be reliable.

Sincerely,

Terry McNamara
F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

FTM/lt

Enclosure: Supplement Report (3)



Transmittal Document

1. Name and Address of Submitter

Miles Inc.
Agriculture Division
Animal Health Products
Box 390
Shawnee Mission, Kansas 66201

F. Terry McNamara

F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager
(913) 268-2588

2. Regulatory Action in Which this Package is Submitted

Data submitted to support the registration of Co-Ral Livestock Insecticide Spray
EPA File Symbol 11556-RRL

3. Transmittal Date

December 8, 1993

4. List of Submitted Studies:

MRID No. Volume

430 57401 1 -

"Acute Oral Toxicity Study with Coumaphos 6.15%
(Co-Ral) in Rats, "EPA Guideline No. 81-1, Miles
Report No. 103294-1, A. B. Astroff, 7 p.

10/21/93

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ACTIVITY REPORT

TRANSMISSION OK

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION
INSECTICIDE-RODENTICIDE BRANCH

Fax Number (703) 305-6596

F A C S I M I L E R E Q U E S T / C O V E R S H E E T
(Please type or print in BLACK INK only)

S E N D F A X T O :

NAME: Terry McNamara
OFF: Miles Inc.
FAX PHONE NUMBER: 913-288-2541
OFFICE PHONE NUMBER: 913-268-2588

F R O M :

NAME: Linda Arington
DIVISION/BRANCH: RD/rod
OFFICE PHONE NUMBER: 703 305 5420
OFFICE ROOM NUMBER: 202
MAIL CODE: 7805C DATE: 10/21/93 TIME: 3
NUMBER OF PAGES (WITH COVER SHEET): _____

S p e c i a l M e s s a g e - - - d e s c r i b e b e l o w :

Copy of the Chemistry inquiries to follow
the ~~from the~~ acute tox. study as still
under review.

Linda

PRODUCT CHEMISTRY REVIEW

740
8/17/93

TO: PM 13 FROM: Reviewer: INDIRA CHAIROLA Date: 08/16/93
EPA REG. NO.: 11556-RRL PRODUCT NAME: CO-RAL livestock Insecticide Spray

FOOD USE () INERTS CLEARED: C (), D (), E () NON FOOD USE ()
21 CFR PARTS 170-199: () TOXIC INERTS LIST 1 (), 2 ()

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry data for your product. ☐ If submitted earlier, provide MRID Number(s). ☐ Your product is not sufficiently similar to the product you referenced.

2. In reference to the Confidential Statement of Formula (CSF), please provide the following:

- ☐ a) pH of product or pH at a specified water dilution.
☐ b) Density of product.
☐ c) Flash point of product.
☐ d) Flash point of product with propellant as per item #6(q) or item #5(c).
☐ e) Flame extension of product including flashbacks if noted.
☒ f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.

(2)
08/13/93

- ☐ g) The upper and lower certified limits of the individually added inerts.
☐ h) Your label claim for Active ingredient is 5.8%. Hence 13b. or 1% by wt. (6.15%) x purity of Technical (90.0%) = 5.54%. This is below the declared label claim of 5.8%. Moreover your certified limits should be bracketed around this amount (Nominal 1%). The limits should be + or - 3% of Nominal 1% when calculated in pure active form.

3. ☒ Based on the current CSF dated 06/29/93, your product will ~~not meet~~ the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.

The CSF will be accepted after the stated corrections are made.

Note: According to our records purity of source product - #11556-11 is 90.0%. All the calculations are based on this concentration.

PRODUCT CHEMISTRY REVIEW (cont'd)

4. ☒ Provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

1. 

2.

3.

4.

5.

The supplier may contact EPA directly referencing the File Symbol or EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are non food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

- ☐ a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with ☐ PR Notice 84-1 for non-aerosol containers for houses and institutional uses or ☐ PR Notice 83-3 for all other uses.
- ☐ b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h) (2) (iii).
- ☐ c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellents).
- ☐ d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.
- ☐ e) Add a footnote to the inert ingredients indicating: Contains aromatic petroleum distillates, xylene or xylene-range aromatic solvent.
- ☐ f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

Do not use this product in or on electrical equipment
due to the possibility of shock hazard.

PRODUCT CHEMISTRY REVIEW (cont'd)

- ☐ g) The terms active ingredient(s) and inert ingredients should be in the same type size, be aligned to the same margin and be equally prominent.
 - ☐ h)
 - ☐ i)
6. In reference to the product specific data requirements, provide the following information:
- ☐ a) Statement of Composition: A complete description of the manufacturing/formulation process. Describe equipment used, mixing time, temperature, pressure, etc.
 - ☐ b) Discussion of Formation of Unintentional Ingredients: A brief description of impurities formed during the manufacturing/formulation process, in packaging or during storage. If you do not expect any impurities during these stages, please so state.
 - ☐ c) Certification of Limits: Upper and lower limits of each active and individually added inert component. The lower limit for the active ingredients must be the same as the label claim in pure active form.
 - ☐ d) Analytical Method: Provide the methods used to analyze for the active ingredients or a full reference for a published method or MRID Number(s).
 - ☐ e) Color: In common terms.
 - ☐ f) Physical State: e.g., solid, liquid, pressurized liquid, etc.
 - ☐ g) Odor: In common terms.
 - ☐ h) Density: e.g., lbs/gallon for liquids or lbs/cu.ft. for solids.
 - ☐ i) pH: Provide pH of product or pH of a specified water dilution.
 - ☐ j) Oxidizing or Reducing Action: Note these characteristics, if any.
 - ☐ k) Explodability: Note these characteristics, if any.
 - ☐ l) Viscosity: Can be expressed in centipoise or centistokes.
 - ☐ m) Miscibility: Note these characteristics if product is an emulsifiable liquid and mixed with oil.
 - ☐ n) Corrosion Characteristics: This information can be noted during the storage stability study.
 - ☐ o) Dielectric Breakdown Voltage: For products used near electrical equipment.

All these data are there and have been found acceptable.

PRODUCT CHEMISTRY REVIEW (cont'd)

- [] p) Storage Stability: The formulated product must be analyzed for its active ingredients at time zero and during one year of storage. The storage should be at warehouse conditions of temperature and humidity and stored in the product's commercial package. Note: For the storage stability study, you may not reference the data on source product concentrate you are using to formulate your product.
 - [] q) Flammability: Flash point/flame extension. The flash point reported exceeds the one expected for this product. Please check and resubmit. Mixtures marketed under pressure, including those containing hydrocarbons, are subject in their entirety to tests indicated in 40 CFR Section 156.10(h)(2)(iii) of the maxipackage. Note that flash points for pressurized liquids are conveniently measured after collecting the expelled liquid from the container in an open cup chilled with dry ice (Refer to Aerosol Guide, CSMA).
 - [] If any of the items are not applicable, write N.A. and explain reasons as specified under chemistry data requirements footnotes. See 40 CFR Part 158.
7. [] The following is the regulatory status of the inert ingredients under 40 CFR 180.1001 for the exemption of the requirement of a tolerance:

8. Additional Comments:

LA

MILES 

Agriculture Division

Animal Health Products

Miles Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 631-4800
Telex: 437269 Miles AHD

August 9, 1993

Ms. Linda G. Arrington
Product Team 13
Registration Division H7505C
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460-0001

Subject: Co-Ral Livestock Insecticide Spray
EPA File Symbol 11556-RRL

Dear Ms. Arrington:

To confirm our phone discussion of this morning, I authorize you to delete the phrase "Confidential - Do not duplicate" from the top of pages 22 - 25 of Miles Report No. 74426. This report was submitted to support the registration of the subject product.

If you have any additional questions, please call me at (913) 268-2588.

Sincerely,

F. Terry McNamara

F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

FTM/lt



superceded by 01/15/93
Labels

Reason to Issue: To propose registration
of a new product

Date: 6/29/93
Page 1 of 8

(Front Panel)

Co-Ral®

(coumaphos)

LIVESTOCK INSECTICIDE SPRAY

For Control of Horn Flies, Face Flies, Lice and Ticks

Active Ingredient:

0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl)
phosphorothioate

5.8%

Inert Ingredients*:

94.2%
100.0%

*Contains aromatic petroleum distillates.

This product contains 0.25 lb 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per half gallon.

EPA Reg No. 11556-XXX

EPA Est. No. 11556-KS-1

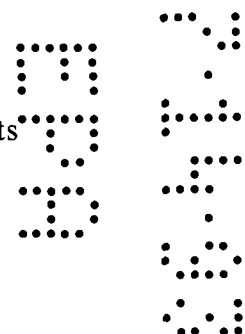
KEEP OUT OF REACH OF CHILDREN

WARNING

SEE BACK AND SIDE PANELS FOR STATEMENTS OF PRACTICAL
TREATMENT AND OTHER PRECAUTIONARY STATEMENTS

NET CONTENTS ½ GALLON

Miles Inc., Agriculture Division, Animal Health Products
Shawnee Mission, Kansas 66201 U.S.A.



(Side Panel)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

STATEMENTS OF PRACTICAL TREATMENT

If swallowed: Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

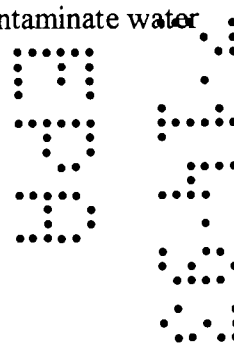
If on skin: Remove contaminated clothing and wash affected areas with soap and water.

If in eyes: Flush eyes with plenty of water. Call a physician immediately.

To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate.



(Side Panel)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not allow to freeze. Keep from extreme heat.

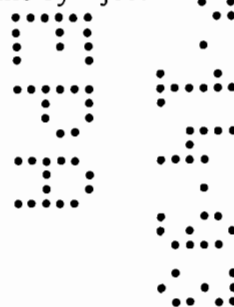
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PROTECTIVE CLOTHING STATEMENT

USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders must wear a chemical resistant apron and face shield or goggles and a NIOSH/MSHA approved respiratory protection device.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Livestock Insecticide Spray has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.



(Back Panel)

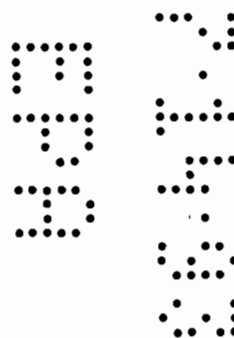
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Co-Ral Livestock Insecticide Spray mixes easily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control.

Spray Treatment for Specified Ectoparasites: Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Livestock Insecticide Spray is ideal for backrubber application. When properly mixed and applied, effective control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Livestock Insecticide Spray for use in backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.



(Back Panel)

RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 8 QUARTS OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY
CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL LIVESTOCK
INSECTICIDE SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENTS: Apply specified dosage for a complete wetting to run-off. Repeat as necessary.
	Ticks	4	10	
	Screwworms	8	20	SPRAY TREATMENT(S): Apply specified dosage as high pressure spray so as to wet the skin, not just the hair, of the animal. Repeat as necessary.
Lactating Dairy Cattle	Lice	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Repeat as necessary. No interval is required between treatment and slaughter or use of milk.

(Continued)

(Back Panel)

ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons of No. 2 fuel oil or No. 2 diesel fuel (or 9 ¾ oz Co-Ral per gallon) . Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. NOTE: For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
(Not intended for slaughter)	Ticks	4	10	Treat thoroughly all wounds and injuries. Repeat as necessary.
	Screwworms	8	20	

(Continued)

(Back Panel)

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Repeat as necessary.

USE RESTRICTIONS

For external insecticidal use only on above-specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Livestock Insecticide Spray per 50 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

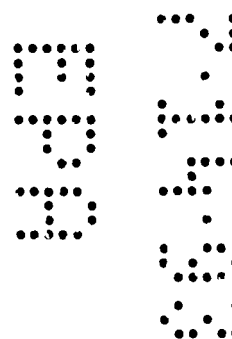
Do not spray in a confined, non-ventilated area.

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

LIMITED WARRANTY AND
LIMITATION OF DAMAGES

Miles Inc., Agriculture Division, warrants that this material conforms to the chemical description on the label. MILES INC. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Miles Inc. is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Co-Ral is a Reg. TM of the parent company of Miles Inc.



Agriculture Division

Animal Health Products

Miles Inc.
P.O. Box 390
Shawnee Mission, KS 66201-0390
Phone: 913 631-4800
Telex: 437269 Miles AHD

Certified P 437 201 931

August 9, 1993

Ms. Linda G. Arrington
Product Team 13
Registration Division H7505C
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460-0001

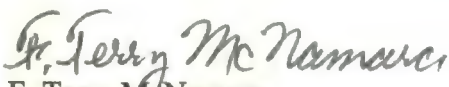
Subject: Co-Ral Livestock Insecticide Spray
EPA File Symbol 11556-RRL

Dear Ms. Arrington:

With regard to the subject application, enclosed are two copies of EPA Form 8570-29 indicating the cite-all method of data compensation. Please discard the earlier forms.

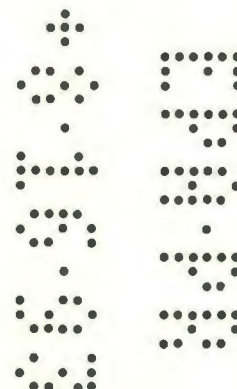
If you have any additional questions, please call me at (913) 268-2588.

Sincerely,


F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

FTM/lt

Attachment: Form #8570-29 (2 copies)





Certification with Respect to Citation of Data

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicants Name and Address

Miles Inc.
Agriculture Division
Animal Health Products
PO Box 390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number

11556-XXX

Product Name

Co-Ral Livestock Insecticide Spray

Date of Application

6/30/93

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)
 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

| | I am the original submitter*; or

| | I have obtained the written permission of the original data submitter to cite that study*
 3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:
 - a. ☒ I am the original data submitter*; or

| | I have obtained the written permission of the original data submitter to cite that study*; or
 - b. | | I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☒ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

| | Those companies that have submitted the studies which I have cited (Selective method*).
- * A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

8/9/93

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

8/9/93

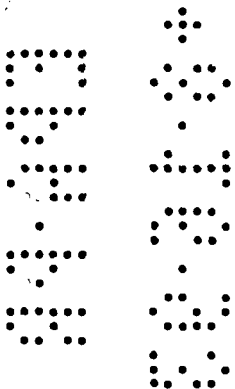
Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to 1.0 hours per response, including time for reviewing instructions, certifying the existence of the appropriate data, and completing and mailing this form. Send comments regarding the burden estimate or any other aspect of this certification process including suggestions for reducing the burden to:

Chief, Information Policy Branch, PM-223
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503





United States Environmental Protection Agency
Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicants Name and Address

Miles Inc.
Agriculture Division
Animal Health Products
PO Box 390
Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number

11556-XXX

Product Name

Co-Ral Livestock Insecticide Spray

Date of Application

6/30/93

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

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2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

☐ I am the original submitter*; or

☐ I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☒ I am the original data submitter*; or

☐ I have obtained the written permission of the original data submitter to cite that study*; or

b. ☐ I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☒ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

☐ Those companies that have submitted the studies which I have cited (Selective method*).

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

8/9/93

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

F. Terry McNamara

Name and Title F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager

Date

8/9/93

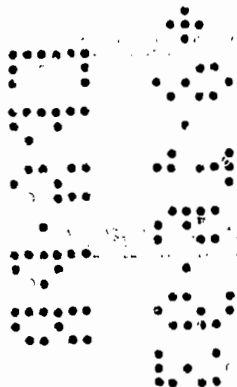
Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to 1.0 hours per response, including time for reviewing instructions, certifying the existence of the appropriate data, and completing and mailing this form. Send comments regarding the burden estimate or any other aspect of this certification process including suggestions for reducing the burden to:

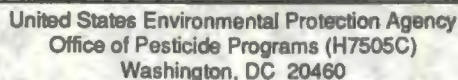
Chief, Information Policy Branch, PM-223
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503



Form Approved. OMB No. 2070-0060. Approval expires 11-30-93



X	Registration
	Amendment
	Other

188386

1. Company/Product Number 11556- XXX RRL	2. EPA Product Manager George T. LaRocca	3. Proposed Classification <input checked="checked" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Miles Inc./ Co-Ral Livestock Insecticide Spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Miles Inc. Agriculture Div., Animal Health Products P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

<input type="checkbox"/>	Amendment - Explain below	<input type="checkbox"/>	Final printed labels in response to Agency letter dated _____
<input type="checkbox"/>	Resubmission in response to Agency letter dated _____	<input type="checkbox"/>	"Me Too" Application.
<input type="checkbox"/>	Notification - Explain below.	<input checked="" type="checkbox"/>	Other - explain below.

See Attachment

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit Package wgt. No. per container		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.		If "Yes," Package wgt. No. per container			
3. Location of Net Contents Information		4. Size(s) of Retail Container		5. Location of Label Directions	
<input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		1/2 Gallon		<input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other (Plastic sleeve around the container)			

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
F. Terry McNamara	Biochemistry and Pesticide Registrations Manager	915: 268-2586

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature
F. Terry McNamara
4. Typed Name
F. Terry McNamara

3. Title
Biochemistry and Pesticide
Registrations Manager

5. Date
June 30, 1993

6. Date Application Received (Stamped)

360

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with a new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Attachment for OPP #188386, Application for Pesticide

With this application, the enclosed data and the enclosed labeling, we are requesting the registration of Co-Ral Livestock Insecticide Spray, EPA Reg No. 11556-XXX. Five copies of the proposed labeling, dated 6/29/93 are enclosed.

Please note, Miles has a similar product - Co-Ral Emulsifiable Livestock Insecticide, EPA Registration No. 11556-23- currently registered. When EPA issued the "Registration Standard (Second Round Review) for the Reregistration of Pesticide Products Containing Coumaphos as the Active Ingredient" (hereafter referred to as the "Guidance Document") in September, 1989, the Agency classified this product (11.6% active ingredient) and our Co-Ral Flowable Insecticide product (42% active ingredient), EPA Reg. No. 11556-98, as Restricted Use Pesticides because of the high acute oral toxicity of these two formulations.

Miles requested additional explanation on these reclassifications. In a November 29, 1990 meeting with the Agency (where this topic and other coumaphos topics were discussed; a copy of the attendance sheet is enclosed). The Agency responded (and a copy of an EPA 2/12/91 Toxicology Branch memo on this subject is also enclosed) that the acute oral toxicity of the 11.6% formulation had an oral LD₅₀ of 50 mg/kg. Consequently, the Toxicology Branch memo states

"An end-use product with an oral LD₅₀ of 50 mg/kg or less will be considered for restricted use [40 CFR 152.170 (a) (2) (i)]. This is the reason why the 11.6% EC formulation requires a restricted-use classification."

In this 11/29/90 meeting, Miles related that as the acute oral toxicity is the only "trigger" for the restricted use classification, if a more dilute, less acutely toxic formulation was developed then the restricted use classification would not be necessary. The Agency responded that this more dilute formulation would be considered a new product, and acute oral toxicity data would be necessary.

Accordingly, this application is for a product which is very similar to Co-Ral Emulsifiable Livestock Insecticide (ELI). The proposed new product contains only one-half (5.8%) of the active ingredient in ELI (11.6%); the 5.8% active ingredient no longer in the new, dilute product has been replaced by an additional 5.8% of one of the inert ingredients (See product chemistry data and discussion below). This new dilute product is less acutely toxic and does not meet the 50 mg/kg acute oral LD₅₀ trigger for restricted use classification.

Product Chemistry. Enclosed is a Confidential Statement of Formula (CSF) for this proposed product. Please note, this CSF contains qualitatively, the same components as the CSF for the ELI (EPA Reg. No. 11556-23). The most recent CSF for the ELI product is dated 1/17/90, was submitted to the Agency on 1/29/90, and was accepted by the Agency on 10/23/91 along with revised labeling for ELI, Co-Ral Cattle Pour-On (EPA Reg. No. 11556-25), and Co-Ral KRS Spray Foam Insecticide (EPA Reg. No. 11556-40) and the CSF's for the 11556-25 and 11556-40 products.

As shown in the enclosed CSF, quantitatively, the formulation for the new product is the same as the formulation for the ELI product with only one exception. The new formulation contains 5.8% less active ingredient and 5.8% [REDACTED].

The product chemistry data for the new product are enclosed as Miles Report No. 74426, entitled "Product Chemistry of Co-Ral Livestock Insecticide Spray (LIS) ½ lb/gal."

Acute Toxicity. As cited above, Miles has conducted an acute oral toxicity study with the proposed new product, and copies of these results - Miles Report No. 103294, entitled "Acute Oral Toxicity Study with Coumaphos 6.15% (Co-Ral) in Rats" - are enclosed. The acute oral LD₅₀ was 1477 mg/kg for males and 395 mg/kg for females.

With regard to the other acute toxicity data requirements, we cite and will accept the acute toxicity values for the ELI formulation which contains 5.8% more active ingredient and 5.8% less [REDACTED] than the new product.

Specifically, the acute toxicity guidelines and EPA MRID Nos. for the corresponding data for the ELI formulation are

EPA Guideline No.	EPA MRID No.
81-2	00112833
81-3	00112836
81-4	00112834
81-5	00112835
81-6	00112837

Also please note, the Agency has reviewed all of these ELI acute toxicity studies and found them to be adequate (see p. 77 of the Guidance Document which lists the acute toxicity data for the 11.6% EC formulation).

Efficacy. As provided for in the regulations, we request that the requirements for efficacy data be waived.

Labeling. The enclosed draft labeling for the proposed product is based upon the most recently accepted labeling (Agency 10/23/91 letter) for Co-Ral Emulsifiable Livestock Insecticide, EPA Reg. No. 11556-23.

Briefly, the proposed labeling does not include restricted use classification for the reasons previously discussed. The signal word and Hazards to Humans and Domestic Animals language are consistent with the Toxicity Category II (oral and inhalation) of this product.

The Statements of Practical Treatment, Environmental Hazards and Storage and Disposal language are identical to that for the 11556-23 product.

The protective clothing statement is also identical with only one exception. The phrase "and dip tank workers" has been deleted because the proposed product does not contain any dip vat uses.

The Directions for Use in the enclosed labeling are very similar to those currently accepted by the Agency for the ELI (EPA Reg. No. 11556-23) product.

For example, the enclosed draft labeling contains the same use restrictions.

All of the uses on the draft labeling are already on the ELI labeling. Moreover, the use rates on the draft labeling are equivalent in terms of active ingredient to the use rates on the ELI labeling. To reflect the fact that the new product contains only one-half the active ingredient contained in the ELI formulation, the enclosed draft labeling contains different dilution directions. Generally the ELI formulation use directions require "X" quarts of ELI to be used to prepare 100 gallons of spray. The enclosed corresponding use directions on the enclosed labeling require "X" quarts of the new product to be used to prepare 50 gallons of spray.

Also, the enclosed labeling contains an additional use directions column for the preparation of an equivalent (in terms of active ingredient) smaller volume of spray - 4 gallons.

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As a specific example, the current ELI labeling specifies 4 quarts diluted to 100 gallons for spray treatment of ticks on beef and non-lactating dairy cattle. The enclosed labeling requires 4 quarts diluted to 50 gallons for the same use. Also, as there are 128 ounces per gallon, or 4 quarts, this use rate is 128 ounces per 50 gallons of spray. Or, in terms of ounces per gallons of spray, the use rate is

$$(128 \text{ ounces}) \left(\frac{1}{50 \text{ gallons}} \right) = 2.56 \text{ oz/gallon}$$

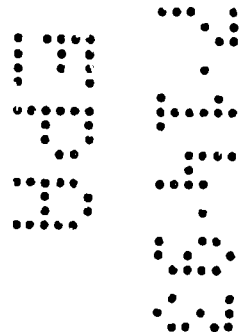
Therefore, the ounces of formulation to prepare 4 gallons of spray equals (4) (2.56 oz/gal) or 10.2 ounces, and the proposed labeling recommends 10 ounces of the new formulation to prepare 4 gallons of spray.

The enclosed labeling does not include the directions for use against grubs, which are in the ELI use directions.

Child Resistant Packaging. This proposed product will not be distributed and sold in child-resistant packaging because this product does not meet the use criterion of 40 CFR 157.22 (b).

FIFRA Section 3 (c) (1) (F) Data Compensation. Included with this application are two completed and signed "Certification with Respect to Citation of Data" forms indicating the General Offer to Pay although all data cited in EPA's September, 1989 "Registration Standard (Second Round Review) for the Reregistration of Pesticide Products Containing Coumaphos as the Active Ingredient," are Miles (formerly Mobay and Bayvet) data or public literature data.

Summary. Enclosed is an application for the registration of a new formulation of coumaphos. This formulation is simply a diluted formulation of Co-Ral Emulsifiable Livestock Insecticide, EPA Reg. No. 11556-23. Moreover, the proposed uses for the new formulation are the same uses (except grub use have been deleted) at the equivalent active ingredient use rates of the 11556-23 product.



AUG 10 1993

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

MILES INC.
AGRIC.DIV.-ANIMAL HEALTH PROD.
BOX 390
SHAWNEE MISSION, KS 662010390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/14/93. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Transmittal Document

1. Name and Address of Submitter

Miles Inc.
Agriculture Division
Animal Health Products
Box 390
Shawnee Mission, Kansas 66201

428745- $\phi\phi$

F. Terry McNamara

F. Terry McNamara
Biochemistry and Pesticide
Registrations Manager
(913) 268-2588

2. Regulatory Action in Which this Package is Submitted

Data submitted to support the registration of Co-Ral Livestock Insecticide Spray
(a new formulation of coumaphos; Mr. George T. LaRocca, Product Manager 13)

3. Transmittal Date

June 30, 1993

4. List of Submitted Studies:

MRID No. Volume

428745 ϕ 1

1 -

"Product Chemistry of Co-Ral Livestock Insecticide Spray (LIS), 1/2 lb/gallon, "EPA Guideline Nos. 61-1 to 61-3, 62-1 to 62-3, 63-1 to 63-21 and 64-1, Miles Report No. 74426, L. D. Thomas, 40 p.

428498 ϕ 1

2 -

"Acute Oral Toxicity Study with Coumaphos 6.15% (Co-Ral) in Rats, "EPA Guideline No. 81-1, Miles Report No. 103294, A. B. Astroff and L. L. Hagen, 20 p.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JUL 20 1993

MILES INC.
AGRIC.DIV.-ANIMAL HEALTH PROD.
BOX 390
SHAWNEE MISSION, KS 662010390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/14/93. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [01] :

A statement which claims data confidentiality appears on one or more pages within the body of the study. Since all data claimed as confidential under FIFRA 10(d)(1)(A), (B), or (C) should have been removed to the confidential attachment, you need to clarify your intentions regarding the data contained in the body of the study.

Transmittal Document

1. Name and Address of Submitter

Miles Inc.
Agriculture Division
Animal Health Products
Box 390
Shawnee Mission, Kansas 66201

428498-ØØ

F. Terry McNamara

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3. Transmittal Date

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MRID No. Volume

Reject (Ø1)

1 -

"Product Chemistry of Co-Ral Livestock Insecticide
Spray (LIS), ½ lb/gallon, "EPA Guideline Nos. 61-1
to 61-3, 62-1 to 62-3, 63-1 to 63-21 and 64-1, Miles
Report No. 74426, L. D. Thomas, 40 p.

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2 -

"Acute Oral Toxicity Study with Coumaphos 6.15%
(Co-Ral) in Rats, "EPA Guideline No. 81-1, Miles
Report No. 103294, A. B. Astroff and L. L. Hagen,
20 p.



REQUEST FORM

CR#: 94-0216

REC'd 05/03/94

REQUESTOR NAME: Linda Arrington

REQUEST DATE: 4/20/94

TEL: (703) 205 8410 ORG: LDC/EDS (DIV./BR./SEC.)

ROOM: 202 MAIL CODE: 20252

CSF ATTACHED:

- ☒ YES If CSF is attached complete Item A and the chemical name in Item B.
☐ NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:

✓ Check Applicable Category

- ☒ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)
☐ Provide PCC for Non-Food Use Inert Ingredient (s)
☐ Provide PCC for Active Ingredient(s)
☐ Provide PCC for Dye
☐ Determine if Fragrance is Acceptable for Use in Formulation
☐ Other (Describe):

B. INGREDIENT INFORMATION:

Ingredient No. 1:

Ingredient No. 2:

Chem. Name:

Chem. Name:

Trade Name:

Trade Name:

CAS Reg. No.:

CAS Reg. No.:

Ingredient No. 3:

Ingredient No. 4:

Chem. Name:

Chem. Name:

Trade Name:

Trade Name:

CAS Reg. No.:

CAS Reg. No.:

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 4136-001 Product Name: Colman's Mustard

Registrant: Miles Inc.

Food-Use Pesticide: ☒ YES ☐ NO

Percent in Formulation (For Fragrance/Dyes only):

INFORMATION REPORTED:

Ingredient No. 1:

Ingredient No. 2:

PCC:

PCC:

TOL STATUS:

TOL STATUS:

OTHER INF.:

OTHER INF.:

Ingredient No. 3:

Ingredient No. 4:

PCC:

PCC:

TOL STATUS:

TOL STATUS:

OTHER INF.:

OTHER INF.:

Completed By: LINDA

FON

Date Completed: 05/03/94

7-100-101

Inert ingredient information may be entitled to confidential treatment

Once completed, this form may be entitled to treatment as CBI under section 10 of FIFRA. If so, a red FIFRA CBI cover should be affixed to the request form and the document handled accordingly.

